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The Concept of Autonomy in End-of-Life Decisions: Ethical and Legal Regulation regarding Advance Directives

Presentata da: **Denard Veshi**

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Chapter 4. Conclusions

Introduction

In this thesis the concept of autonomy in end-of-life decisions is analyzed through ethical and legal comparative approaches in view of the fact that this field is one of the main fields where law and ethics are so closely intertwined. The definition of advance directives – living wills and the appointment of a legal proxy – is studied. In addition, Recommendation CM/Rec (2009) 11 and the "Guide on the decision-making process regarding medical treatment in end-of-life situations" is analysed.

Currently, end-of-life decisions are part of the exclusive competence of national parliaments. Thus, different parliaments have adopted different policies underpinned by different moral principles. What follows is an absence of a common European legal framework. National laws on advance directives in various Western European countries – such as Romance-speaking countries (Italy, France, Portugal, and Spain), English-speaking countries (Ireland and the United Kingdom of Great Britain and Northern Ireland), and German-speaking countries (Austria, Germany, and Switzerland) – are examined. This thesis seeks to analyse national norms governing advance directives by hypothesising the reasons for the lack of a common attitude towards end-of-life decisions and to identify similarities and differences between countries, in addition to advancing some proposals for the future regarding end-of-life decisions.

Particular attention is paid to the current Italian situation regarding end-of-life decisions, since – within our survey, which includes the analysis of national laws in the Romance-, English-, and German-speaking countries – Italy, in addition to Northern Ireland and the Republic of Ireland, is one of the few Western European countries being analysed that does not have a specific law governing end-of-life situations. While in Northern Ireland the biomedical community adopts the *Mental Capacity Act*, and in Ireland the *Assisted Decision-Making (Capacity) Bill* 2013 and the *Advance Healthcare Decision Bill* 2012 are under public discussion, in Italy the issue of the end-of-life is quite complex. Herein, the Italian bill no. 2350 "Provisions relating to therapeutic

alliance, informed consent, and advance directives for treatments" – approved in different texts in 2009 by the Senate and in 2011 by the Chamber of Deputies – is criticized because its norms are considered controversial. Similarities and differences between Bill no. 2350 and the eight proposal bills of the current legislation – which began on 15 March 2013 – are highlighted. Additionally, the judicial interpretation of amended Articles 404–413 of the Italian Civil Code – which introduced to Italy the legal role of the support guardian (*amministratore di sostegno*) – is examined. This examination is fundamental because Italian judges have applied these articles to fill the gap in the Italian legal system regarding the role of the legal proxy in the dying process, sometimes conferring on the guardian powers that are similar to those of the surrogate.

The aim of the thesis is to identify the common European standards in end-of-life decisions. Moreover, similarities and differences between different policies will be pointed out. Furthermore, possible suggestions for modifying the Italian bill 2350 by taking the experience of other Western European countries into consideration will be made.

This thesis is divided into four main chapters. The definition of advance directives (ADs) is studied, and two main types of advance directives are distinguished. Several main critiques of the recognition of the significance of ADs – such as life having an intrinsic value (or there is a principle of sanctity of life), ADs distorting the patient-physician trust and misunderstanding the social role of physicians – are examined. In addition, in cases where end-of-life decisions will be taken by the legal proxy, some results of empirical studies have shown their dubious motives; also, the possibility that they lose their capacity is discussed. However, although these problems exist, this thesis suggests that the benefits of ADs still outweigh the risks because advance directives should be considered an instrument that safeguards patient autonomy and highlights patient-physician trust.

Moreover, the concept of relational autonomy is analyzed by taking into account the criticisms made of the individualistic approach to autonomy. The

disadvantages and shortcomings of living wills and the importance of the role of the legal proxy in end-of-life decisions are pointed out through ethical and moral reasons. In addition, examples from the legal norms or from court rulings which underline the position of the surrogate are examined. Furthermore, the results of empirical studies are laid out. Different court rulings are studied. Particular attention is paid to the Italian case law in *Eluana Englaro*, since Italy is one of the few Western European countries that does not have any specific law governing advance directives. In addition, the political and social reaction to it is discussed.

The main results of Chap. 1 regard the significance of ADs, and in particular the role of the legal proxy, in end-of-life decisions; the relational approach to autonomy, which positively contributes to improving the patient-physician relationship; and the role of the courts' rulings in filling the gap created by the lack of specific legal rules governing end-of-life situations.

The position of the Council of Europe and of the European Court of Human Rights (ECtHR) is analyzed. It should be noted that the legal reasoning done by the ECtHR is based on the European Convention on Human Rights (ECHR). Nevertheless, its reasoning can perfectly be applied to the interpretation of the European Convention on Human Rights and Biomedicine of April 1997 (the so-called "Oviedo Convention"), since the preamble of Oviedo Convention cites the ECHR, and the convention of 1997 can be seen as *lex specialis* relative to the ECHR of 1950 in the biomedical field (Application no. 8278/1978). A special focus is given to the latest ruling of the ECtHR, the ruling in *Lambert* (e.g., see Sec. 2.1.1.1.).

The latest documents published by the Council of Europe are analyzed. More precisely, Recommendation CM/Rec(2009)11 of the Committee of Ministers to member states on principles concerning continuing powers of attorney and advance directives for incapacity of December 2009 and the *Guide on the decision-making process regarding medical treatment in end-of-life situations* (hereafter, the *Guide*) of May 2014 are examined. The Recommendation CM/Rec(2009)11 is studied by giving concrete examples of

internal legislation from English-, German-, and Romance-speaking countries. The *Guide* on the decision-making process of May 2014 is analyzed through ethical reasoning by taking into consideration the application of the well-known set of ethical principles as suggested by the US-American ethicists Beauchamp and Childress (1979) and the role of the parties in end-of-life situations. The second part of Chap. 2 is dedicated to the legal situation in English-, German-, and Romance-speaking countries. Within them, legislation in four countries – Spain, France, England, and Germany – is analyzed in detail because the other countries in this survey take a similar legal, ethical, or political approach to one of these.

This thesis shows – through concrete examples from national laws – the existence of a basic common European standard. Moreover, the possibility of an application of Recommendation CM/Rec(2009)11 by the European Court of Human Rights is suggested, even though this document is considered *soft law*. In addition, the importance of the public debate regarding ethical issues in end-of-life situations is pointed out through commentary on the *Guide.* In the conclusion, the difference is analysed between the approaches taken to ADs in national policy in Romance-speaking countries on one side and the English- and German-speaking countries on the other: this analysis is based on the role that physicians have in end-of-life situations.

A particular attention is given to the situation in Italy in comparison with several European models. The interpretation of the different legal concepts used or of the rules established in the Convention on the Rights of Persons with Disabilities, the bioethical debate regarding withdrawing alimentation and hydration (ANH), the rigidity forms established for the validity of ADs or for the appointment of a surrogate, and the political decision made in regard to cases involving the absence of a surrogate for the patient are criticized. Moreover, the legal interpretation of amended Articles 404–413 of the Italian Civil Code (C.C.), introduced by law no. 6 of 9 January 2004, is studied. Italian judges have applied these articles to fill the gap in the legal system regarding the role of the legal proxy in the dying process.

The main results of Chap. 3 regard the analysis of the position of the Italian bioethical and medical communities and the position of the jurisprudence in recent decades. This investigation highlights the bioethical community's change of approach from a complete paternalist one in 1993 to a liberal one in 2014. In addition, the jurisprudence has applied Articles 404–413 C.C. to fill the gap in the Italian legal system regarding the role of the legal proxy in the dying process. All these parties (bioethical and medical communities and the jurisprudence) have underscored the importance of *ad hoc* rules governing end-of-life situations.

In the last part of this scientific work, conclusions are presented. After highlighting the significance of ADs in end-of-life decision-making, a basic consensus on patient autonomy and subsequently on the patient's right to self-determination is presented through the position of the Council of Europe and the rulings of the ECtHR. Moreover, the results of the analysis of Recommendation CM/Rec (2009)11 of December 2009 and of the *Guide* on decision-making of May 2014 – while considered *soft law* – show the common European standard in this area. Moreover, after studying the national laws in the English-, German-, and Romance-speaking countries, a division between Romance-speaking countries, on one side, and the English- and German-speaking countries, on the other, is defined based on the involvement of physicians in the end-of-life process and the risks arising from the execution of advance directives. Furthermore, some possible modifications to the Italian bill are suggested, based on the experience of existing European legislation. In addition, an interpretation of Articles 404–413 C.C., which considers the legislative intent of Italian lawmakers in 2004 and the patient's right to self-determination recognized in the Italian Constitution (Articles 13 and 32), is proposed.

Chapter 1: End-of-Life Decisions and the Right to Autonomy

Abstract

The concept of autonomy in end-of-life decisions is analyzed through ethical perspective and case-law studies. Several scholars have demonstrated that although ethical and moral principles are often considered absolute and unchanging, they are actually dynamic and evolving since they are defined largely by society and medical law and ethics are necessarily influenced by these principles. From one generation to the next and between countries, changes in culture, values, and social structure have resulted in substantial shifts in the limits of what is morally and ethically acceptable regarding end-of-life issues and other topics in bioethics.

In addition, in end-of-life decisions the public discussion is continues because it touches upon people's most intimate interests, which have traditionally involved religious and other personal values. National legislators have difficulties to rule this topic. It follows that the process of the promulgation of a law is slower compared to the transformation of the society. Therefore, judges have substituted national legislators by deciding in single case-law.

The definition of advance directives – living wills and the nomination of a legal proxy – is studied. Although several main criticism regarding the recognition of the significance of advance directives – such as life having an intrinsic value, advance directives distorting the patient-physician relationship and misunderstanding the social role of physicians – are considered, this contribution suggests that the benefits of advance directives still outweigh the risks because advance directives should be considered the main instrument that safeguards patient autonomy.

The concept of relational autonomy is analyzed by taking into consideration the critiques directed at the individualistic and liberal approach

to autonomy. The relational approach to autonomy takes into consideration the influence that external factors have on the individual decision making process, in addition to increase the patient's trust in the physician's role by contributing positively in the patient-physician relationship.

Moreover, disadvantages and shortcomings of living wills and the importance of the role of the legal proxy in end-of-life decisions are pointed out through moral argumentations. The main shortcoming of living wills regards the fact that it is quite impossible for people without a medical background to foresee the evolution of all diseases and to establish in advance specific medical treatments. Thus, if a concrete medical situation arises that was unforeseeable for the patient, the previously written-down directives might become insufficient or inapplicable. This exposes a considerable weakness of living wills.

Different court rulings are examined. National judges have protected patient autonomy by interpreting, sometimes through complex legal argumentations, the fundamental human rights. Particular attention is given to the Italian case-law of *Eluana Englaro* since Italy is one of the few Western European countries that does not have a specific law governing advance directives. Moreover, the same legal reasoning is recently adopted by the Italian Council of State in its ruling of 2 September 2014, no. 4460.

The aim of first part of this work is that to underline the significance of advance directives through ethical approach and case-law studies.

1. The connection between ethics and law in end-of-life decisions

In recent decades there has been a transformation of the scope of medicine: from the strict medical concept of health to the broader concept of well-being (World Health Organisation 2012), where the approach of shared decision-making is the main goal (Swetz et al. 2014, Tibaldi et al. 2011, and Beltran 1996). Before, patient health was promoted solely according to physicians' medical and scientific expertise (Devettere 2010). Since then, the patient's right to self-determination has increased (Gabl and Jox 2008) and several European legislators have regulated ADs[1]. Therefore, physicians must take

[1] Within the English-, German- and Romance- speaking countries, the laws on advance directives in chronological order (by date of approval by the national parliament) are: in Scotland: *Adults with Incapacity (Scotland) Act* of 29 March 2000; in Spain: *Básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica',* law no. 41 of 14 November 2002*;* in England *Mental Capacity Act* of 7 April 2005 (the same legislation has been adopted by the Wales Parliament on 13 March 2007); in France - *Loi relative aux droits des malades et à la fin de vie,* law no. 2005-370 of 22 April 2005 (However, nowadays, the French Senate is discussing a new Bill *Loi relative au choix libre et éclairé d'une assistance médicalisée pour une fin de vie digne* submitted on 2 December 2013, bill no. 182); in Austria: *Bundesgesetz über Patientenverfügungen (Patientenverfügungs-Gesetz – PatVG),* law no. 55 of 8 May 2006 and *Sachwalterrechts-Änderungsgesetz 2006 – SWRÄG 2006,* law 92 of 23 June 2006; in Switzerland: *Schweizerisches Zivilgesetzbuch (Erwachsenenschutz, Personenrecht und Kindesrecht)* of 19 December 2008 entered into force in 1 January 2013; before that, the treatment of incapacitated patients fell under cantonal legislation); in Germany: *Drittes Gesetz zur Anderung des Betreuungsrechts*, law no. 593 of 19 June 2009; in Portugal: *'Regula as diretivas antecipadas de vontade, designateadamente sob a forma de testamento vital, e a nomeação de procurador de cuidados de saúde e cria o Registo*

into consideration not only patients' health but also their wellbeing, which is a broader concept than health, because it includes patients' individual and subjective ideas of health (Wiesemann and Alfred 2013).

Recently, the patient's active role has been acknowledged in several international conventions, such as the European Convention of Human Rights of 1950, the European Convention on Human Rights and Biomedicine of April 1997, the Hague Convention on the International Protection of Adults of 13 January 2000, and the Charter of Fundamental Rights of the European Union of 2000, which from 1 December 2009 has the same legal status as EU Treaties (C. Cost. 24 October 2007, no. 348 and no. 349) (e.g., see Chap. 2).

Therefore, the traditional approach towards end-of-life decision-making in Europe has changed: death is no longer considered a natural event but a long process of steps involving medical treatment where the definitions of duty of care and quality of life have become ever more ambiguous, contentious and controversial (Zullo 2010).

The advances of medicine have brought the existence of a grey zone between life and death within which the promulgation of life or the

Nacional do Testamento Vital', law no. 25 of 16 July 2012. In Ireland, the *Assisted Decision-Making (Capacity) Bill* 2013 and the *Advance Healthcare Decision Bill* 2012 are under public consultations. There is no statutory law in Northern Ireland. In Italy, the bill 2350 '*Provisions relating to therapeutic alliance, informed consent and advance directives for treatments*' is the only act which has been debated by the Italian deputies and senators in different texts in 2009 by the Senate and in 2011 by the Chamber of Deputies.

anticipation of death depend on the individual's or the doctor's decision to allow or reject life-sustaining treatment. New medical discoveries can prolong the life of a patient with incurable disease for long time. The best examples are those of patients in a vegetative state where the person is not dead but has lost mental activity and consciousness (e.g., see Sect. 1.5.1. and 3.1.1.).

Less than seventy years ago, end-of-life decisions were considered a taboo topic. Before 1965, the term *quality of life* was not indexed in the Medline database, which is the largest and most widely used index of the medical literature (Lacroix and Mehnert 2002). This began to change in the late 1960s in the USA (Forbes et al. 2009), where the individualistic approach to is common than in Europe. In 1969, the physician Elisabeth Kubler-Ross published her book entitled "On Death and Dying" that lead to the promotion of a public discussion about the roles and needs of terminally ill patients and their families. From that time, in the USA, medicine has moved from a paternalistic model to one that promotes autonomy and self-determination (Teres 1993). Therefore, the patient-physician's trust (Thom et al. 2011, and Thom and Campbell 1997) and the psychological preparation for death (Karen 2000) have been considered fundamental. This approach has been further been supported by the 'new' interpretation of the patient autonomy as a relational principle. This new interpretation of the concept of autonomy is considered more useful than the previous concept of autonomy as formal right to self-determination because it takes into consideration that external factors influence the individual decision making process (e.g., see Sect. 2.2.). Recently, the *Guide on the decision-making process regarding medical treatment in end-of-life situations* has underlined this concept (e.g., see Sect. 2.1.3.). In addition, the relational approach of autonomy is in harmony with the empirical studies that highlight the importance of the surrogate in end-of-life situations (e.g., see Sect. 1.4.1.), which has also been underlined by the Council of Europe in the Recommendation CM/Rec (2009) 11 (e.g., see Sect. 2.1.2.).

There is no other field like biomedicine where law and ethics are so closely intertwined. Law and ethics create a web of duties, obligations, rights

and recommendations (Hoppe and Miola 2014). In medicine, the types of obligations come from both the legal and the ethical systems. A legal duty can be prescribed in the law or in the medical guidelines established by the Chamber of Physicians or by the hospital. A moral obligation is one that individual is thought to have towards others in a society. One of the most famous legal positivists of the early twentieth century, George Jellinek (1908), stated that "law is nothing other than the ethical minimum". The scope of law is that to create rules regarding the peaceful societal cohesion. It follows that the law must cover the minimum of moral norms required for this cohesion.

In addition, both law and ethics use moral notions. While law often emphasizes moral notions, ethics uses them to develop an argument for or against a certain course of action. Therefore, ethics would not be possible without morals (Hoppe and Miola 2014). In addition, in end-of-life situations, the law is based on the moral notions shared in that specific society. Also, this interconnection has been recognized by judges. For instance, in the ruling of the Court of Appeal Bland, the judge Hoffmann LJ stated that "this [end-of-life decisions] is not an area in which any difference can be allowed to exist between what is legal and what is morally right" ([1993] 1 All ER 821 at 850, (1993) 12 BMLR 64 at 95). This view was further supported by the House of Lords in the opinions of Lord Browne-Wilkinson and Lord Mustill. The concern about law and moral values in end-of-life situations is strong since it touches upon people's most intimate interests, which have traditionally involved our religious convictions and have provoked intense emotions (Manson and Laurie 2011).

This interconnection is facilitated also by the fact that both law and ethics use the same conceptual categories: rules, principles, rights, procedures (van der Burg 1998). Both them are focused on recent medical practice based on liberal theory, in which autonomy and patient rights are central, and not on ideal situations. The work of ethicists is both orientated at and influenced by the law. This could seem controversial because while legal theories are based on reasons of proof based on external acts rather than internal intentions,

many ethical theories take the opposite approach and focus on the internal process of decision making.[2] Moreover, since bioethical norms are principles, rules could be achieved only through deductive logic (Richardson 2005).

In the 21st century, ethicists are chosen as experts by court or European parliaments to assist with the legal regulation of biomedicine. European legislators have highlighted the close relationship between ethics and law by establishing bioethical committees. In addition, when a physicians have to deal with terminal ill patients, they do not only need medical knowledge but also legal and ethical expertize (e.g., see Sect. 2.1.3.). Recently, this has been confirmed also by the Council of Europe in the publication of the *Guide on the decision-making process regarding medical treatment in end-of-life situations*.

Studying end-of-life decision-making is interesting because more and more people get into situations where they have to consciously confront the topic of dying. This is partly due to a general increase in life expectancy and of chronic and/or terminal diseases. In addition, there is a medical trend towards early diagnosis of progressive conditions. Moreover, European citizens pay more attention to their health and their rights in end-of-life

[2] This difference seems particularly emphasized in case of euthanasia. While ethicist would focus on the principle of autonomy, in addition to the fact that some scholars will go beyond the distinction between act and omission, lawyer would consider external acts such as the active act to inject a high doze of morphine. Thus, for lawyers, increasing of doze of painkillers will be considered – except the countries that have legalized euthanasia, such as the Netherlands and Belgium, - as a criminal offence.

situations. It follows that some younger people, as a precaution against unexpected illness or accidents, will nominate a surrogate (Council of Europe 2009).

Acute death due to infectious disease – such as cancer and cardiovascular disease – has been replaced by diseases, which have more protracted dying process. Advances in new medical technologies have greatly improved possibilities to treat seriously ill patients and to prolong life. Additionally, since the beginnings of the 21 century empirical research has shown a rise in life expectancy. According to Eurostat, over the past 50 years, life expectancy has increased by about 10 years for both men and women in the EU zone (Eurostat 2014).

This trend has been supported by several factors such as the introduction of public health care services, medical and technological progress, the improvement of environmental conditions, improvement in education, healthier lifestyles and an overall rise of "socio-economic status". Therefore, the majority of deaths nowadays are the result of non-sudden events or diseases.[3] Also, the majority of people in Europe die in hospitals, from which it follows that they have several dialogues with their physicians about the last period of their life (Ashcroft 2005). This allows the patients to

[3] The study of Euroled showed that only one third of all the death between June 2001 and February 2002 in six European countries (Belgium, Denmark, Italy, the Netherlands, Sweden, and Switzerland) happened suddenly and unexpectedly (e.g., see Sect. 1.2).

decide on the type of their medical treatments or whether to withhold or withdraw them.

In the past, death and the process of dying were a matter of private decision done within the specific socio-cultural and religious background; nowadays, end-of-life decisions have become a matter of ethical debate and of public policy. The increase of medical discoveries, which has been followed by the increase of life-expectancy and the decrease of sudden death, has stimulated national legislators to rethink the traditional legal norms regarding end-of-life situations. Moreover, the patient-physician trust and patient autonomy have been highlighted.

1. The European legal models analyzed

In this thesis the legal situation in Romance-speaking countries (Italy, France, Portugal, and Spain), English-speaking countries (Ireland, and United Kingdom of Great Britain and Northern Ireland), and German-speaking countries (Austria, Germany, and Switzerland) is analyzed. However, it should be noted that although some countries give legislative authority concerning health issues to their regions, this thesis looks only at national laws.

A particular attention has been given to the law in Spain, France, England, and Germany, since these countries have been considered them as

paradigmatic cases, because the other countries in this survey take a similar legal, ethical or political approach to one of these. The Spanish law, for instance, has been used as a model by the Portuguese Parliament.[4] The Italian bill of 2009 (re-proposed in 2011 and by the proposal-bill 2229 in 2014) shares its political motivation with the previous version of the French law of 2005,[5] which recently has been modified[6]. The English Mental Capacity Act of 2005 recognizes similar principles to those of the laws of the other English-speaking countries.[7] In German-speaking countries, national legislators have

[4] The Portuguese law no. 25 of 16 July 2012 established that advance directives must be obeyed except in three different cases established in its article 5 as well as cases that are similar to the cases established by article 11, section 3 of the Spanish law no. 41 of 14 November 2002.

[5] As in France, the Italian bill no. 2350 – approved with modification in 2011 and still not passed – was the result of the case-law of Eluana Englaro.

[6] The *Loi créant de nouveaux droits en faveur des malades et des personnes en fin de vie* is more liberal because ADs are presumed to be legally binding and without time-limit.

[7] The Welsh Parliament adopted the same act as England on 13 March 2007. In Northern Ireland, there is no law on ADs; however, the bioethical community asks for the implementation of the English Mental Capacity Act of 2005 (British Medical Association 2007). In Scotland, ADs are governed by the Adult with Incapacity (Scotland) Act of 2000, and in Ireland the Assisted Decision-Making (Capacity) Bill 2013 and the Advance Healthcare Decision Bill 2012. Both these acts share the principles of the English model, since both focus on a person's capacity and confer a similar power of control over the legal proxy's activity to the Courts and to the Office of the Public Guardian.

adopted the same political approach: assuming that end-of-life decisions are an individual matter, they have modified their civil codes.[8]

The conceptualisation of dying is culturally located within a particular level of socio-economic development, cultural expectations, and intergenerational relations (Grande et al. 2009, Hales et al. 2008, Kellehear 2008, Howarth 2007, and Seale 1998) (e.g., see Sect. 1.2.). In addition, since the scope of law is the individuation of the "ethical minimum", different legislator have highlighted different moral values. In particular, the Spanish law of 2002 is dedicated to the promotion of information in the field of health[9]. Nevertheless, also in Spain the importance of the role of physicians has been highlighted. In France, the previous law no. 2005-370 of 22 April 2005 has been considered a reaction to the case-law of Vincent Humbert, a tetraplegic patient who publically claimed the right to euthanasia (Pereira 2007, and Dupont 2005). The previous law of 2005 was the only law within the Romance-, English- and German-countries analysed that directly

[8] It should be noted that in Austria there are two laws governing ADs. The law of 8 May 2006, *Patientenverfügungs-Gesetz – PatVG*, regulates 'living wills'; the law of 23 June 2006, *Sachwalterrechts-Änderungsgesetz 2006 – SWRÄG 2006*, rules 'der Bevollmächtigte', the legal proxy nominated by the patient when fully competent. Only the law of 23 June 2006 modifies the Austrian Civil Code by introducing in articles 284f-284g the 'Bevollmächtigte'.

[9] The Law 41 of November 2002 emphasize the right to health information, informed consent, health documentation, clinical records and other clinical information; rights that were insufficiently ruled from the General Health Law of 1986. (Cesáreo et al. 2004)

recognizes the advisory power of ADs and the only one that has modified its *Code de la Santé Publique* (CSP, Public Health Code). This law has adopted such a paternalistic approach that some authors have compared the situation in France with that of the USA in the 1990s (Rodríguez-Arias 2007). However, it must be noted that the new law of 2015 is much more liberal, although it has confirmed the importance of the physician-centred approach by confirming the *ad hoc* collegial proceeding established in article 1111-4, section 5 and article 1111-13, section 1 and adding the new case in the article 1111-5-1, section 1 CSP.

The German model is of great interest because the law presupposes the legally-binding nature of ADs, is considered rather liberal, and modifies the *Bürgerliches Gesetzbuch* (BGB, civil law) (Wiesing 2010). In addition, no other Western European legislation analyzed in this thesis has explicitly acknowledged such a strict decisive power of previously uttered verbal expressions. The Mental Capacity Act (MCA) of 2005 reflects the English liberal tradition – which goes back to the work of Locke (1690) and Mill (1865) – and protestant influence (Dickenson 1999). Moreover, in England, the patient's right to self-determination is considered fundamental by the bioethical community (General Medical Council 2008, and General Medical Council 2010), physicians (Horn 2014) and judges (Airedale NHS Trust [1993] 2 WLR 816; Re B [2002] 2 All ER 449.; Re T [1992] 4 All ER 649.; Re T [1993] Fam 95; Re C [1994] 1 All ER 819; Re MB [1997] 2 FLR 426 (CA)).

Furthermore, the Mental Capacity Act shares similar principles with the other English speaking countries;[10] principles that have been used as model for the new bill in Ireland.[11]

[10] The Walsh Parliament on 13 March 2007 has adopted the same legislation as England. In Northern Ireland, there is no statutory law ruling ADs; however, the bioethical community asks for the implementation of the English Mental Capacity Act of 2005. (British Medical Association 2007). In Scotland, ADs are governed by the Adult with Incapacity (Scotland) Act of 2000, which is similar to the English model. Both these acts focus on citizen's capacity. In addition, both these acts recognize to the jurisdiction organ similar power of control regarding the legal proxy's activity (in England: the Court of protection, article 22-33 of the Mental Capacity Act; in Scotland: the power of the sheriff, article 3 of the Adult with Incapacity (Scotland) Act). Furthermore, in both these countries, a third party (in Scotland, it must be a solicitor) certifies that the person who gives the power of attorney and the person who accept this power have understood their roles and duties (in England: the relationship between donor-donee must be certified article 7.7. Code of practice of the Mental Capacity Act; in Scotland: the solicitor certifies the relationship between granter-welfare attorney ex article 15 of the Adult with Incapacity (Scotland) Act). Moreover, the 'surrogate will' must be registered at the Office of the Public Guardian (article 7.14 English Code of practice of the Mental Capacity Act; in Scotland: article 23 of the Adult with Incapacity (Scotland) Act). In both these English-speaking countries, an independent organ with the purpose of assisting with information or advising legal proxies has been established (in England: the Independent Mental Capacity Advocate Service, article 35-41 of the Mental Capacity Act. In England this body can also nominate a legal proxy in case that there is no AD; in Scotland: the Mental Health Commission, article 9 of the Adult with Incapacity (Scotland) Act).

[11] In Ireland, the Assisted Decision-Making (Capacity) Bill 2013 and the Advance Healthcare Decision Bill 2012 are under public discussions. However, both these bills are similar to the Mental Capacity Act 2005. For instance, some similar principles between the Assisted Decision-Making (Capacity) Bill 2013 and the Mental Capacity Act could be withdrawn. First of all, as in England, the focus of this bill is the mental capacity of the donor. The relationship between the person who gives the power of attorney and the person who accept this power is defined donor-attorney, where attorney is called the 'donee of an enduring power' (article 38). Moreover, the role of

Particular attention will be given to the situation in Italy. Although, the new proposal-bills[12] will be taken into consideration, the main analysis will be based on the bill 2350 '*Provisions relating to therapeutic alliance, informed consent and advance directives for treatments*' from a comparative legal perspective. Although this bill has not passed into law, this act is the only bill which has been debated by the Italian deputies and senators in different texts in 2009 by the Senate and in 2011 by the Chamber of Deputies[13]. Additionally, none of the new proposals have been discussed by the permanent commissions of the Italian Parliament. Moreover, one of the latest the proposal – that from Ms. Roccella and others on 26 March 2014 – establishes exactly the same principles as the controversial bill of 2009, amended in 2011.

the judicial body (which will be exercised by Circuit Courts and in some specific cases by the High Court) and the role of the Public Guardian have been underlined. As in England, the Court can decide directly or through an appointment of a decision-making representative (article 23; in England this person is called 'deputy' ex-article 16 of the Mental Capacity Act). Also, the role of the Public Guardian has been demonstrated from the fact that the power of attorney must be registered at the Office of the Public Guardian (article 43).

[12] None of the five proposals from the Chamber of Deputies has yet been discussed by the XIIth Commission on Social Affairs. The same applies to the three proposals from the Senate, that are assigned to but not yet discussed by the XIIth Permanent Commission on Hygiene and Health.

[13] The Italian Parliament has two chambers: the Chamber of Deputies and the Senate. In Italy, a draft bill becomes law only if the two chambers approve it the identical form. Bill no. 2350 was approved in two different versions by the Italian Parliament: in 2009 by the Senate and in 2011 by the Chamber of Deputies. However, it should be highlighted that constitutional bill A.S. 3520, which is being debated in the Italian Parliament at the time of writing, aims to change Title V of the Italian Constitution, which establishes the organization of the Legislative Power.

Furthermore, the new Italian Code of Medical Ethics of May 2014 confirms the paternalistic approach of bill 2350 (e.g., see Sect. 3.1.). In addition, the *Circulaire*[14] of 19 November 2010 of the Ministry of Health in accordance with the Ministry of Welfare State and Ministry of Internal Affairs states that all the ADs that citizens have deposited in their Municipalities are ineffective,[15] since civil status and register offices are subjects that fall under the exclusive legislation of the State (article 117, section 1, let. i. Italian Constitution) and the State Parliament has not yet established the principles. As a result, all the local laws in Italy that govern ADs are null[16].

[14] The *Circulaire* is an internal act, used by the Italian Public Administration, which contains recommendations regarding its internal operation. This act produces legal effects only within the public administration; its legal effects cannot be applied to citizens or other legal persons who are not part of that organ.

[15] According to the Italian civil law, an ineffective act is less than a null act. In case of a null act, the production of legal effects is null *ex tunc*, but, in case of ineffective act, the act never produced any legal effect.

[16] The National Association of Italian Municipalities stated on 21 November 2010 that the Italian Municipalities: 1) have collected the certification that the citizen has written an AD (without collecting the AD); and/or 2) have collected the AD; and/or 3) have established AD's forms. While the second and the third activities could be considered *contra legem* since there is a lack of national legislation, the collection of a certification where the citizen declares that he or she has written an AD, probably also by stating where the AD has been deposited, is legal since the Municipality is offering an administrative service regarding the population and the local territory. Precisely, this is a service to the individual and to the community established in article 13, section 1 Legislative Decree 267 of 18 August 2000. Moreover, as a reaction to this *Circulaire,* Italian Municipalities have only established the possibility to collect the citizens' certifications that they have written an AD (Govi et al. 2013).

The need to analyze different laws comes from the fact that several European studies – such as those by Ethicus,[17] Eureld,[18] Ethicatt,[19] and Prisma[20] – have shown the range of approaches to end-of-life decisions. These studies analyzed the questionnaires from terminally-ill patients (Ethicus); from physicians in different specializations in which death is common (Eureld); from physicians, nurses, patients and their families (Ethicatt); and from the general population (Prisma). However, it should be noted that in Europe, a basic consensus on patient autonomy has been formulated in the Council of Europe and in the case-law of the European Court of Human Rights. Some of the most important documents from the Council of Europe are: *Guide on the decision-making process regarding medical treatment in end-of-life*

[17] The Ethicus group analyzed questionnaires from patients in intensive care units (ICUs) in 17 European countries (Belgium, Czech Republic, Denmark, Finland, Germany, Greece, Ireland, Israel, the Netherlands, Portugal, Spain, Sweden, Switzerland, Turkey and the United Kingdom) in 1999–2000 (Sprung et al. 2008, Sprung et al. 2008, Sprung et al. 2007, and Benbenishty et al. 2006)

[18] The Eureld group studied questionnaires completed by physicians from different specialisations in which death is common in six European Countries (Belgium, Denmark, the Netherlands, Sweden, and Switzerland) in 2001–2002 (Cohen et al. 2008, Löfmark et al. 2008, Buiting et al. 2007, van Delden et al. 2006, and Bilsen et al. 2006).

[19] The Ethicatt group examined questionnaires from physicians and nurses working in ICUs, patients who survived ICU, and their families in six European countries (Czech Republic, Israel, The Netherlands, Portugal, Sweden, and the United Kingdom) in 2004. (Bülow et al 2012, Sprung et al. 2007, and Vrakking et al. 2007)

[20] The Prisma group studied surveys completed by the population in 7 different European countries (England, Belgium, Germany, Italy, the Netherlands, Portugal and Spain) (Daveson 2013).

situations of May 2014, Resolution 1859 (2012) of 25 January 2012, Recommendations CM/Rec(2009) 11 of 9 December 2009 and R(99)4 of 23 February 1999, Convention on Human Rights and Biomedicine of April 2007. The recent case-law of the European Court of Human Rights regarding right to decide medical treatments are: applications no. 34806/04; no. 23459/03; no. 2346/02; and no. 302/02 (e.g., see Sect. 2.1.).

3. Moving beyond the limits of individualism model of autonomy: the concept of relational autonomy

The concept of patient autonomy was developed in USA in the late 1960s. This concept was predominant not only in medical ethics, but also in other social movements, where it emphasised the individual's right to have control over his/her body and the decision-making process. Physicians paternalism, and therefore the ethical principle of non-maleficence and beneficence, where argued. Doctors were not allowed anymore to withhold information from patients and their families or to make decisions based on their perspective of the patient *physical* best interest. Doctors were viewed not only as experts of medicine, but also as professionals obliged to provide to patients – consumer of health care services – with information regarding their health.

Nowadays, almost half a century after the enhancement of patient autonomy, the bioethical community is discussing what 'respect for autonomy' should be considered. The answer depends on which model of autonomy that is embraced. The two main models of autonomy are: the individualist model and the relational autonomy.

The traditional model is characterized by prioritizing rational over emotional abilities. This theory is based on the writings of John Stuart Mills (1806–1873) and Immanuel Kant (1724–1804). The Kantian approach assumes the individual as capable of rational reasoning to do and to decide what is morally right (Beauchamp and Childress 2001). Instead, Mills defines

autonomy through a negative approach: autonomy is the freedom from the interference by others, including state agencies (Woods 2007). According to scholars that apply an individualist approach, "the autonomous man is – and should be – self-sufficient, independent, and self-reliant, a self-realizing individual who directs his efforts toward maximizing his personal gains. His independence is under constant threat from other (equally self-serving) individuals" (Code 1991). In other words, there is an ambivalent relationship between autonomy and individualism.

The main focus of the individualistic model is the rejection of influence of external factors on the individual decision making process. The reliance on the opinion of others – especially, in our context, the physicians' opinion – would be considered highly suspicious (Degner 1997). Rationality is the main factor of this cognitive approach. If the process of deciding is overshadowed by emotions – such as fear, anger, or grief – one's self-control is compromised. It follows that this individual is not autonomous anymore. The role of the physician is to give cognitive information without interfering with the individual's decision-making process; physicians should not give recommendations but only neutral information (Owens 2013). Since the centre is in the individual self-determination, the patient should be self-sufficient and able to recognize the interference of others and to ignore them.

The focus on the cognitive process of deciding is a direct result of the analytic philosophy, characterized by an emphasis on argumentative clarity and precision. Etymologically, the term autonomy means 'self-rule' in Greek, or the capacity of self-determination and self-government (Skilbeck and Payne 2005). This approach has been adopted by the utilitarian and neoliberal schools and from the majority of the western European countries. According to the liberal interpretation of autonomy, self-determination is the capacity to make decisions without the interference of external factors. The individualistic model stresses the decisional capacity: the reasoning behind the deliberative decision assumes a fundamental importance (Frankfurt

1989). According to this model, the person is considered a 'rational isolated thinker'.

The main critiques of this model regard the lack of influence that external factors should have. Firstly, since the individualist model does not allow physicians to give personal recommendations or opinions, this decreases the patient's trust in the physician role by contributing negatively to the ability to fully exercise his/her autonomy (Owens 2015, and Entwistle 2010). Secondly, the traditional model is insensitive to the diverse personal and circumstantial differences, which shape the patient's decision. Several studies have shown that decisions depend on several factors, such as age (Gomes 2011), gender (Biggs 1998), ethnicity (Venkatasalu et al. 2011, and Worth et al. 2009), culture (Howarth 2007), availability of careers (Lavoie et al. 2011), family dynamism (structure and relationships) (Broom and Kirby 2013), interpersonal relationships (Rini et al. 2011, Corrigan 2004, and Lewis and Rook 1999), and complexity of the disease (Thomas et al. 2004). A neo-liberal approach to autonomy fails to recognize the complexity of the decision (Wilson et al. 2014). Thirdly, it is quite difficult to apply the individualist model in concrete medical situations. The patients' capacity could be damage when they undergo surgery or faze disability. It is common that during therapy, patients are inconsistent. They might change their decisions according to the prognosis, which modifies their prospective regarding what they want for themself. Moreover, this model does not provide the resources to evaluate the ethics of risky patient choices (Hunt and Ells 2011). Fourthly, the reality of people's lives is one of interdependency (Zelderloo 2009). This leads to the question: how can physicians evaluate the patient's decision without taking into consideration the external factors that shape the patient's decision making process?

In the 1980s, feminist bioethical scholars started to question the individualist approach of autonomy. The gender difference emphasises certain aspects of moral knowledge, which has led to the development of ethics of care. Autonomy was seen not as an individualist moral norm but as relational

autonomy, which is premised on the shared conviction that persons are socially embedded and that their identities is formed within the context of social relationships (Mackenzie and Stoljar 2000). In this approach, social relationships are considered fundamental. While the individualist model considered the person as an isolated island, the concept of relational autonomy highlights the social network and the influence of external factors. Social relationships are so important that a person is seen as a 'second person' (Baier 1985). Several scholars have distinguished these two types of autonomy also as *internalist*, focusing only on the decision-making process, and *externalist*, which considers also the external circumstances, in particular the social relationships. Therefore, these are the individualistic and the relational models (Shakespeare 2015, Ashley 2013, and Oshana 2006).

Relational autonomy is an 'umbrella' term, which seeks to clarify personal autonomy in a method that highlights the role of cultural and economic factors, and especially the role of social relations (Mackenzie and Stoljar 2000). This model considers identity and interest as dynamic and continuously shaped by relationships with other people. In addition, emotions are not undervalued and the dialogue with the physician is stressed as the only way to allow autonomy to fully flourish. Through the relational model, autonomy can be supported on a broader level, where interpersonal and external factors are highlighted (Biggs 1998).

While the individualist model will consider as non-autonomous the person who relies on the opinions of others, with the relational model it is not unreasonable for a patient to defer his/her decision to another person. With the new model of autonomy, the role of the legal proxy – especially that of the surrogate – is accentuated: family members, physicians, relatives or other interested parties have the moral obligation to co-operate to help the patient in the difficult decisions regarding end-of-life situations. The importance of emotions in general – not only empathy – is crucial, especially in palliative care (Walter 2014).

In end-of-life decisions, patient-physician trust and dialogue are fundamental. Therefore, the influence coming from this relationship should be considered as well as the mental capacity of the patient. People behave differently with different people; several case-laws have demonstrated that while some assessors have considered a person incapable – since there was a lack of co-operation – others have considered the same person capable to decide (Wandsworth Clinical Commissioning Group [2014] EWHC 990 (COP); Re JB [2014] EWHC 342 (COP)). The relational approach to autonomy stimulates the patient-physician partnership. Doctors will share all the information with the patient (and his/her family and/or relatives) and spend more time with the patient. This approach leads to an enhancement of patient autonomy (Hunt and Ells 2011). Obviously, it entails administrative and economic problems because hospitals might not have budgets to support this policy.

In the last decades, several scholars have emphasized the concept of relational autonomy. In addition, in November 1998, twenty-two partners – coming mainly from the Romance-speaking countries – signed the Barcelona Declaration (policy proposals)[21]. Its significance is based on the fact that this document is a philosophical and political agreement between experts in

[21] The Barcelona Declaration was the result of three years and four big meetings (Copenhagen, Sheffield, Utrecht, and Barcelona) between the partners. Its aim was to stimulate the public debate on some of the most conflict-prone questions regarding within Europe (and not within E.U.). It should be noted that the public debate was acknowledged also in the Convention of Oviedo of April 1997.

bioethics and bio-law from many different countries, making a conceptual clarification and articulation of major ethical principles (Kemp and Rendtorff 2008). This Declaration states that the main ethical principles are autonomy, dignity, integrity, and vulnerability[22]. The combination of autonomy and integrity leads to the enforcement of the concept of relational autonomy. While autonomy remains an ideal because of its structural limitations due to human weakness and dependency on external factors or lack of information (Rendtorff 2002), integrity – understood as inviolability of the human being under a narrative approach (e.g., see Sect. 1.4.1.) – is the most important principle for the creation of patient-physician trust, because it requires physicians to listen the life story of their patients (Kemp et al. 2000). Moreover, these basic principles are promoted in the framework of solidarity and responsibility (Kemp and Rendtorff 2008); therefore, the dialogue between parties is essential.

It should be stressed that the concept of relational autonomy has been interpreted in several different ways. Nevertheless, all scholars agree on the causal role that the personal and environmental circumstances might have upon their deliberative capacity of a person. The two main current of

[22] Autonomy should not only be interpreted in the liberal sense of "permission" but instead as a set of five different capacities (principle 1). Dignity should not be reduced to autonomy (principle 2) (Knoppers 1991). Integrity accounts for the inviolability of the human being (principle 3). Vulnerability concerns integrity as a basic principle for respect for and for the protection of human and non-human life (principle 4).

relational autonomy are: *procedural relational autonomy* and *substantive relational autonomy*. Procedural relational autonomy considers autonomy as a psychological process. This is similar to the individualist approach. Nevertheless, it differs from it by acknowledging that a person's deliberative process will be subject to external factors such as social relationships and socialization (Ben-Ishai 2012). The substantive relational autonomy looks beyond the deliberative process of decision-making (Oshana 2006), by considering the broader concept of acting. Therefore, there is a shift: from the process of *deciding* to the broader concept of *acting*. While the first model considers a decision a mental process, the substantive relational autonomy sees it as a result of a person's interaction with the social conditions needed to pursue the goal.

Probably the best example to understand this difference is the case of an elderly person living alone at an isolated home from health care system making a decision about whether to accept more accessible and better serviced accommodation. According to the procedural relational autonomy based on the process of deliberation the decision of this person is autonomous. However, based on the substantive relational autonomy model, where the social environment is fundamental and takes into consideration the all acting, his/her decision could be not autonomous. This depends on how much the absence of these accommodations has influenced this person. Linking the evaluation of autonomy with external factors – material or social – leads to the question: what opportunities in particular are important for granting agents autonomous action?

One of the most important theories that include the main part of the substantive relational autonomy model is the concept of 'capability approach of autonomy', developed initially by Amartya Sen and then by Martha Nussbaum. The capabilities approach perceives a person's capacity for autonomous action in terms of the capability he/she has to achieve certain states that they recognize to be valuable. According to Sen, the decision depends on the person's capability to *do* and *become* the objects of his/her

choosing through the conversion of potential capabilities into actual *functionings* (Sen 1985). This view is shared by Martha Nussbaum too (Nussbaum 2000). In addition to that, she stated a list of basic capabilities and essential *functionings* that a person must have access to if he/she is to be autonomous in any meaningful sense. One of them is the 'capability to be healthy'. Being healthy is not something that people may simply want but a precondition needed by citizens to be able to live a flourishing and autonomous life (Prah Ruger 2010). This is why health is considered a constitutional right (e.g., see Sect. 2.2.).

Concluding, the relational autonomy model was developed by the feminist bioethical scholars in the early 1980s. According to the relational approach to autonomy, autonomy is premised on the shared conviction that persons are socially embedded and that their identity is formed within the context of social relationships.

4. The significance of advance directives

ADs should be considered as medical statements, which based on the principle of prospective autonomy, give instructions for future medical care (De Boer 2010). These declarations are executive only in the event of future incapacity.

With the recognition of the importance of ADs, a patient's position evolves from a passive role of personal, physical, and mental protection to an active role of freedom and quality of life. However, within the bioethical community there is no unique definition of quality of life. Some scholars think that this concept should be defined objectively by focusing on the physical ability of the individual to function within the society (Hunt 1986); others argue that this concept is subjective, centered on personal life satisfaction (Albrecht and Devlieger 1999); yet other scholars try to combine these approaches (Shumaker and Berzon 1995).

Patients can choose between several medical treatments or they can refuse them. The right to self-determination is not limited, because in the legal system no law imposes a duty to live (C. Cass. 16 October 2007, no. 21748). Therefore, there is no physician's "right to care" (C. Cass. 30 July 2004 no. 14638). The right to self-determination can be compromised only in cases where a public intervention aims to protect others' health and does not damage, but improves patient's health (C. Cost. 22 June 1990, no. 307; C. Cost., 23 June 1994, no. 258; C. Cost., 18 April 1998, no. 118).

The acknowledgement of patients' values and preferences is fundamental. This could be achieved with a process of only four steps: understanding, appreciation, reasoning and communicating a choice (Karel 2007). [23] It is fundamental that the agents comprehend diagnostic and treatment-related information (understanding). After understanding the risks and benefits of a particular medical treatment, patients must have the ability to relate them to their own future eventual particular situation (appreciation) by comparing alternative treatments in a logically consistent manner (reasoning). At the end, they should convey a treatment choice (communicating a choice).

[23] The same proceeding has been established also in the *Guide on the decision-making process regarding medical treatment in end-of-life situations*, 2014, p. 16-17. (e.g., see Sect. 2.1.3.)

4.1. The main critiques regarding the recognition of advance directives

The main critiques of the recognition of ADs are: life has an intrinsic value (or there is a principle of sanctity of life); they distort the patient–physician relationship; and they misunderstand the social role of physicians. In addition, specific criticisms have been made of ADs that nominate a surrogate.

Some bioethicists claim that life has an intrinsic value. Catholic bioethicists would state that ADs infringe the principle of the sanctity of life. It should be pointed out that the concept of 'sanctity of life' has a religious connotation that should not be used by a secular state (Brock 2009). One objection derived from this principle is that if patients have the right to decide about their end-of-life, life will be less valued. Sick people could be considered less important than healthy citizens (Spoto 2011). People with disabilities and old patients without families could ask for treatment to be withdrawn because they do not have families or relatives to take care of them.

The second main criticism focuses on the patient–physician dialogue. A competent patient can make a decision and can reconsider it after taking into account physicians' advice. However, an incapacitated patient cannot revise his/her medical declarations. Furthermore, if ADs are general or vague or include only specific treatments that cannot be applied by analogy to a given medical situation, there will be difficulties in interpreting patients' wishes (Teno et al. 1998).

Physicians' social role could be considered as professionals who want to keep their patients alive, even through aggressive treatment. Physicians' perceptions of patients who could have written ADs, but did not, could be that these patients want to undergo aggressive treatment, or that these patients "did not want treatment withheld under any circumstances" (Kelly 2006).

Moreover, in every case where a decision should be made by a surrogate, proxy decisions entail several specific problems. Patients' decisions change over time, so it may be quite difficult for surrogates to understand

patients' values (Witting 2008). As it was mentioned in Chap. 1, according to some philosophers, such as Derek Parfit (1984) and others (Wolf et al. 1991), personal identity is discontinuous over time and place. When the grade of psychological continuity falls below a certain minimum level, a person's identity is disrupted, and we can no longer speak of the same person (Parfit 1985). This is emphasized in cases of patients with dementia, where as a result of the progress of dementia, one body can house successive selves.

In addition, empirical studies have shown that some surrogates – due to clinically diagnosed conditions, such as stress, depression, and anxiety – can lose their capacity (Siegel 2008). Additionally, sometimes "some may have dubious motives in that they are looking out for their own interests rather than the patient's interests" (Pope 2012).

Although these problems exist, it should be suggested that the benefits of ADs still outweigh the risks. Further, in case of incapacity, ADs can create a bridge between patients and physicians (Italian Bioethical Committee 2003, British Medical Association 1995). Moreover, ADs – especially if were expressed through an intensive dialogue with doctors – enhance patient's autonomy (Hunt 2001). In addition, only the recognition of ADs will lead to the equal treatment of competent and incompetent patients, which entails an application of the principle of equity.

5. The two forms of advance directives

Patients can express their medical declaration (basically)[24] in two different forms, which are not necessarily mutually exclusive and could be complementary[25]. In addition, it should be noted that from a medico-legal prospective, these types of ADs should be complementary (Bundesärztekammer 2013, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research 1983).

[24] It is interesting to note that the various types of AD, from declarations with legally binding power (advance directives) to advisory opinion, where wishes are expressed and do not aim to modify other's actions (advance statements); from opt-in directives that are irrevocable (Ulysses contract) – existing in Scandinavian countries for some types of mental disorders such as psychotic depression, bipolar disorder, recurrent mania – to opt-out directives that are always revocable when the agent is of sound mind (living wills under English law); from declarations that pertain only to medical treatments (advance directives, advance statements, advance agreements, Ulysses contracts) to declarations that also apply to other issues such as leisure activities, sleeping habits, food, smoking, religious activities and so forth (advance directives in mental health). Lastly, we should note the cases of advance agreements and Nexum contracts, where patient–physician communication is highlighted, and there is an agreement between these two agents that in case of a Nexum contract works basically as a contract (Atkinson 2007).

[25] The clearest distinction between 'living will' and nomination of a legal proxy in the Portuguese law no. 25 of 16 July 2012 and from the legal situation in Austria, where 'living wills' and the nomination of a legal proxy are governed by two different laws (law no. 55 of 8 May 2006 and law 92 of 23 June 2006).

The first type of AD is the so-called living will[26]. The term "living will" is confusing for people because wills take effect only after an agent's death, and are directed to other people (Spoto 2011). ADs are intended to conform a physician's acts to a living patient's wishes. To avoid this confusion, it should be better to use the term *instructional directives* or *treatment directives*. These documents are written expressions of agents' preferences regarding specific medical treatments that they want (to consent to or) to reject in case of future incapacity. It is thought that their origin could be the "Do Not Resuscitate" orders that physicians used to write in patients' case histories after discussing it with them and their families (Rabkin 1976). Therefore, in this thesis, living will should be considered as the document in which the writer[27] expresses his or her preferences regarding specific medical treatments that he or she wants to consent to or to reject in the case of absence of future capacity.

[26] It should be noted that in Sect. 2.1.2., it has been applied a different definition of advance directives. While in this thesis the meaning of advance directives has a broader sense, in the section regarding the study of the Recommendation (2009) 11 of the Council of Europe, the term of advance directives has been used in the narrow sense. It has been applied this methodology because within the provision of the Recommendation (2009) 11 the definition given to advance directives is similar to the definition that it has been given to 'living wills', one of the two main types of advance directives.

[27] Some national rules use specific legal notions to define the person who writes an AD. For example, in England and in the Irish bill the term 'donor' is used (article 9 of the Mental Capacity Act of 2005 and article 38 of the Assisted Decision-making (Capacity) Bill 2013); in Spain, 'ortogante' (article 11 Law no. 41 of 14 November 2002; official translation: 'executor'); and in Scotland, the 'granter' (article 16 of the Adults with Incapacity (Scotland) Act 2000).

It should be noted that in case of clear instructional directives that correspond perfectly in concrete medical situation, they should always have more weight in the decision-making process (Council of Europe 2014) [28]. These could be the cases of chronic illnesses or neurodegenerative diseases effecting cognitive faculties. In these cases, the patient has received all medical and legal information regarding his future (probable) incapacity; unfortunately, these are rare cases (e.g., see Sect. 1.4.1.).

The second type of ADs, the so-called surrogate directive, is a written document, which appoints a surrogate[29]. The surrogate has the authority to

[28] However, there exist some cases that even when clear future medical directives exit, the Court has decided to nominate a legal proxy to interpret them. One of the most famous case decisions is the German case-law Bundesverfassungsgericht: 2001, BVerfG NJW 2002, 206 = 1 BvR 618/93, 2 August 2001 (e.g., see Sect. 1.4.1.)

[29] Some of the phrases used to indicate this legal proxy are: in France, 'personne de confiance' (article 1111-6 French Public Health Code; official translation: 'patient's personal advocate'); in Germany, 'Bevollmächtigte' (article 1901a German Civil Code; official translation: is 'authorised representatives'); in Ireland, the 'attorney' (article 38 Assisted Decision-making (Capacity) Bill 2013); in England, the 'donee of lasting power of attorney for donor's personal welfare' (article 9 of the Mental Capacity Act of 2005); in Scotland 'welfare attorney' (article 16 of the Adults with Incapacity (Scotland) Act 2000); and in Spain, 'representative' (article 11 Law no. 41 of 14 November 2002; official translation: 'representative'). In the other countries, where we did not find an official translation, the legal notion used to indicate this legal proxy are: 'Bevollmächtigte' in Austria (article 284f ABGB); 'fiduciario' in Italy; 'procurador de cuidano de saùde' in Portugal; and 'Vertrauensperson' or 'Vorsorgebeauftragter' in Switzerland (article 378 ZGB). In Switzerland, the surrogate could be nominated also from 'Vorsorgeauftrag' (Precautionary Mandate); in this case the surrogate has the power to manage even the patient's property. A surrogate nominated in the 'Vorsorgeauftrag' must take decisions about the patient's health in accordance with the surrogate nominated in the 'Patientenverfügung'.

make health care decisions on the agent's behalf once the agent is declared incapable. The surrogate is an "extension" of the patient's right to self-determination (Buchanan and Brock 1990). Thus, the patient' representative must suppress his own judgment in favor of 'channeling' what the patients would have done (Frolik 2007-2008). The surrogate must make the medical choice that the patient would have made if he or she had been capable; the surrogate must not make the decision for himself or herself. Therefore, in this thesis, the 'surrogate will' has been defined as the document that nominates a legal proxy who has the power to make health care decisions on the patient's behalf once he or she lacks capacity.

The majority of the bioethicists agree that, in case of a patient's incapacity, medical decisions at end-of-life must be made according to the so-called *three-step hierarchy* in the following order: 1) patient's wishes, 2) substitute judgments and only at the end 3) patient's best interest (Buchanan and Brock 1990). In the first case, patients communicate with physicians through instructions in ADs. In cases of medical instructions that fit perfectly in that specific situation, the role of surrogates is considered as a "mere" reporter (Braun et al. 2009). Unfortunately, these are rare cases because it is quite impossible for people without a medical background to predict the evolution of all diseases and to establish in advance specific medical treatments. However, nowadays, this *hierarchy* is not always so clear[30].

[30] For instance, the German case-law BVerfG NJW 2002, 206 = 1 BvR 618/93, 2 August 2001, the article 25, section 2, let. b) of the Mental Capacity Act of 2005 in

Therefore, a combination between the patient's previous medical directives and the opinion of a legal proxy has a stronger effect (Escher 2014).

In end-of-life decision making, the majority of medical decisions are based on the *substitute judgment*, which was recognized for the first time in the USA in the case of Karen Quinlan in 1976 (70 N.J. 10(1976) 355 A.2d 647) and then used in the Italian High Court of Cassation in the famous case of Eluana Englaro in 2007 (C. Cass. 16 October 2007, no. 21748) (e.g., see Sect. 5.1.). This means that the patient's wishes are inferred from his/her prior statements and/or behavior. The surrogate must take into account any evidence of the patient's religious, spiritual, personal, philosophical, and moral beliefs.

Only when a surrogate does not have all the information needed to make a substitute judgment will medical decisions be made based on the principle of the patient's best interest. A patient's interest must not be limited to the patient's physical health, but must consider also the patient's well-being, which includes psychological comfort. The best-interest standard includes objective factors such as quality of life or life expectancy, clinical standards, and the patient's prognosis.[31]

England and Wales, and in Ireland, article 6, section 2, let. b) of the Advance Healthcare Decision Bill 2012.

[31] Specifically, proxies must take into consideration: (1) the patient's present levels of physical, sensory, emotional, and cognitive function; (2) the quality of life, life expectancy, and prognosis for recovery with and without treatment; (3) the various

5.1. Moral reasons for supporting the role of the legal proxy in end-of-life decisions

Arguments for the importance of legal proxies (surrogates and guardians) in end-of-life decision-making will be put forwards. After examining the disadvantages and shortcomings of living wills, advantages of surrogate are shown to resolve some of the problems with living wills. The ethical reasoning of the legal proxy (surrogate or guardian) is the same.[32]

In case of instructional directives, commonly known as living wills, citizens express their preferences regarding specific medical treatments that they want to permit or to reject in case of future unconsciousness (British Medical Association 2007). This kind of ADs entails several problems. First of

treatment options and the risks, side effects, and benefits of each; (4) the nature and degree of physical pain or suffering resulting from the medical condition; (5) whether the medical treatment being provided is causing or may cause pain, suffering, or serious complications; (6) the pain or suffering to the patient if the medical treatment is withdrawn; and (7) whether any particular treatment would be proportionate or disproportionate in terms of the benefits to be gained by the patient vs the burdens caused to the patient (Pope 2011).

[32] An example that shows the similarities between surrogate and guardian is the German law *Drittes Gesetz zur Anderung des Betreuungsrechts*, law no. 593 of 19 June 2009, where rules established for guardian ('der Betreuer') also apply to surrogate ('der Bevollmächtigte') (article 1901a, section 3; article 1901b, section 3; article 1904, section 5 of BGB).

all, many of these instructions are vague, ambiguous and therefore useless as a basis for treatment decisions (Neitzke 2013, and Fagerlin 2002).[33] Citizens find difficulties in foreseeing future illness, disease and disability and what their medical needs and options will be because they cannot project into their health future (Rubin 2010). Further challenges lie in predicting future medical discoveries and developments: treatment options might change between the time the living will is written and the time at which it is exercised (Braun et al. 2009). Moreover, this kind of ADs does not consider the fact that patients' choices change over time (Ditto et al. 2006), particularly when facing severe diseases (Witting et al. 2008, and Ditto et al. 2003). Did the patient's preferences change over time? Did he or she conscientiously amend the living will or not? According to some philosophers, such as Derek Parfit (1984) and others (Wolf et al. 1991), personal identity is not so much a question of continuity over time and place. Livings wills do not reflect well the fact that patients' choices change over time[34] and particularly when facing severe diseases (Witting 2008).

[33] It should be noted that living wills usually are applicable in cases of permanent and irreversible medical states, such as PVS, the immediate dying process, or advanced stages of dementia. Most living wills refer to these statuses and refuse live prolonging treatment if such situations occur.

[34] One of the most famous case decisions where although there were clear future medical directives the Court decided to nominate a legal proxy to interpret them is the German case-law Bundesverfassungsgericht: 2001, BVerfG NJW 2002, 206 = 1 BvR 618/93, 2 August 2001. In this case the patient was a competent adult Jehovah's Witness who was temporarily unconscious and had refused blood transfusion

Although not without its own problems, the second form of ADs, the 'surrogate will', gives lasting power for health care affairs to another competent citizen, whom in this thesis will be called the 'surrogate'. Surrogates must understand patients' wishes and value (Bramstedt 2003, and New York State Task Force on Life and the Law 1987). They are considered to be an expression and extension of the patients' right to self-determination. In addition, surrogates must make the medical choice that the patients would have made if they had been capable (Buchanan and Brock 1990).

The 'surrogate will' is the best option to resolve well-documented problems that arise with interpretation of living wills (Olick 2014, and Kish et

through clear statements. The German Court decided to nominate a legal proxy – her husband. He expressed doubts about her living will, based on the idea that her actual wish had changed; thus, a blood transfusion was undertaken. The German Constitutional Court decided that it was correct to nominate a legal guardian, to protect patient's rights. It should be noted that his wife has never sued her husband for making a decision against her (apparent) wishes. In 2009, the law *Drittes Gesetz zur Anderung des Betreuungsrechts*, law no. 593 of 19 June 2009, fixed a clear order within ADs in article 1901b BGB, which states that in case of patient's unconsciousness this order must be followed: 1) living will 2) treatment wishes (this is a specific German concept that refers to specific oral declaration that matches the patient's actual medical situation) 3) presumed wishes 4) patient's best interest (which in Germany is understood according to objective medical criteria). Although living wills are considered the primary way to determine patients' wishes, the law is entirely dedicated to the role of legal proxy (surrogate and guardian). Moreover, the legal proxy *"must examine whether these determinations correspond to the current living and treatment situation"*. (Article 1901a, section 1 B.G.B.). Finally, even in Germany – where the law is clear regarding the order within AD – several scholars, such as Stephan Sahm, Christian Zieger and Klaus Dörner, criticize the absolute direct application of living wills without taking into consideration other elements.

al. 2001). Furthermore, since ADs are understood as a culturally embedded tool of self-interpretation (Schicktanz et al. 2010, and Schicktanz et al. 2009)[35], his role has been highlighted since 1982 in USA (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research 1982), then in 1998 in England (General Medical Council 1998), and recently in Italy (National Council of Bioethics 2014).

Instructional directives interpreted by a surrogate who additionally takes into account the patient's values and preferences avoids all the problems connected with changes of opinions from the moment of drafting the 'living will' to that of its execution. Moreover, due the fact that patients' preferences change during the course of a disease (Carmel and Mutran 1999, Berger and Majerovitz 1998, and Ditto et al. 2003), the surrogate has greater opportunity to establish the actual patient's wishes compared with the 'living will', which is a fixed document written at a particular time. This fact has been contemplated by national Court's ruling (BVerfG NJW 2002, 206 = 1 BvR 618/93) and by national legislator[36] that have considered surrogate's judgment fundamental.

[35] In addition some studies have demostrated this connection: (Pecanac et al. 2014, Carrion et al. 2013a, Carrion et al. 2013b).

[36] In Germany, the law is directed to the role of legal proxies (guardian and surrogate). According to article 1901a, section 1 *Bürgerliches Gesetzbuch* (BGB, German Civil Code) the legal proxy must examine whether these determinations correspond to the current living and treatment situation. In addition, in England, article 25, section 2, let. b) of the Mental Capacity Act of 2005 states that previous AD

Moreover, empirical researches have shown that patients mostly would prefer to leave health decisions to others[37]. In addition, generally patients prefer to nominate a surrogate to interpret their wishes rather than decide in advance regarding their medical treatments[38].

The concept of surrogacy highlights the narrative approach to personal identity, which sees lives and biographies as stories (Macintyre 2007). In addition, all the solutions offered to the problem of personal identity, which do not consider the narrative dimension fail (Ricoeur 1995). Further, the narrative approach fits nicely with the substitute judgment principle (Steinbock 2009). The surrogate must take the decision that best continues the themes of the patient's life narrative (Brody 2003, and Blustein 1999).

is not valid if after the donor has conferred to the lasting power of attorney the authority to give or refuse consent to the treatment to which the advance decision relates. The same legal reasoning has been established in Ireland (article 6, section 2, let. b) of the Advance Healthcare Decision Bill 2012). Moreover, in France, the new article 1111-4, section 3 *Code de la Santé Publique* (CSP, French Public Health Code) modified on March 2015 states that in case of hospitalization, it is proposed to the patient to designate a surrogate. This designation is valid for the duration of hospitalization, unless the patient decides otherwise. As it is seen, the French law considers the surrogate's decision fundamental.

[37] In USA, two big studies regarding the implementation of ADs were done during the last decade of the second millennium. These studies have shown that patients leave their health decisions to their family and physician instead of having their own preferences expressly followed (70.8% in HELP and 78.0% in SUPPORT). (Puchalski et al. 2000, Tsevat et al. 1998, and Teno et al. 1997).

[38] In the SUPPORT study, two-thirds of ADs were a 'surrogate will' (Hawkins et al. 2005, Teno et al. 1997, and Sehgal 1992).

Therefore, if the patient was always a strong autonomous individual who valued an active life, the story is better concluded by a chapter telling of a quick death from natural causes, rather than being kept alive for years in vegetative state (Blustein 1999).

This approach fits perfectly in Mediterranean areas where people identify strongly with their communities and therefore it is easier for surrogates to know how patients would have decided had they been conscious (Spinsanti 1992). Moreover, empirical researches have shown that in Southern Europe patients' family are typically given more information than patients themselves (Menaca et al. 2012) – which could be explained by the traditional Catholic approach to truth – and where the majority of informal caregivers are patients' relatives (Costantini et al. 2008, Rossi et al. 2007, Toro et al. 2007).

6. The position of national courts in some of the most important case-laws

Here, some of the most important case-law in some Western European countries will be exposed. Medical law is influenced by moral issues, which depend on the society (e.g., see Sect. 1.1.1.). The process of the promulgation of a law is slower compared to the transformation of the society. Therefore, judges have substituted national legislators by ruling in single case-law. Moreover, the analysis of the national case-law is important because "bio-law is determined by a large degree of openness (….) of the judicial system to the outside world of politics and culture" (Rendtorff 2002).

Since different societies might highlight different moral values, national case-law can differ from each other. For instance, in all the English-, German-, and Romance-speaking countries – except the UK and Austria – dignity, integrity and human rights are explicitly written into the constitution. However, in the United Kingdom and Austria, legislators are more focused on

autonomy (Rendtorff 2002). It should be recalled that dignity should not be reduced to autonomy (principle 2 of the Barcelona Declaration, and Knoppers 1991) (e.g., see Sect. 1.2.).

Traditionally, the law has protected the physician's autonomy. This has recently been confirmed by the Portuguese law of 2012 that has codified the medical objection (article 9 law 25 of 16 July 2012). In last decades, the promotion of patient autonomy has been highlighted by several scholars (e.g., see Sect. 1.2. and 1.3.). As it has been explained above, the approach towards patient autonomy has changed: from the neo-liberal and utilitarian approach – which is based on the cognitive process of deciding – to the relational approach of autonomy – which not only considers the patient's mental capacity but external factors as well, especially the patient's social network. While according to the individualist model of autonomy doctors should give 'neutral' information, the new approach, based on the ethics of care, demands physicians to engage in a broader dialogue and take on a more active role. It follows that doctors frequently find themselves operating in an atmosphere of legal uncertainty. Thus, within this triangular relationship – medicine, ethics, and law – the major purpose of medical jurisprudence is to break down any barriers of latent hostility (Manson and Laurie 2011).

In France, the two most important case-law are the case of Vincent Humbert (Trib. Boulogne sur Mer, 27 February 2006) and of Vincent Lambert (e.g., see Sect. 2.1.1.1.). These two cases are in contrast with each other. The case-law of Mr. Vincent Humbert is really interesting since the previous law ruling ADs, law no. 2005-370 of 22 April 2005 (the so-called Leonetti law), was considered a political reaction to it (Horn 2013). Mr. Humbert was a tetraplegic patient who, through the media, publically claimed the right to die. Since the local authorities did not grant his wish, his mother injected him with a high dose of barbiturates that plunged her son into a coma. Then, Dr. Chaussoy, decided to withdraw the life-sustaining treatment. In addition, to ensure that Mr. Humbert would have not continued to live in a vegetative state, Dr. Chaussoy decided to inject him with potassium chloride. After Mr.

Humbert's death, his mother and his physician were incriminated for "administration of toxic substances" and for "poisoning with premeditation". Finally, the case was dismissed in 2006 with neither being found guilty of a crime. While Mr. Vincent Humbert in 2003 demanded the right to die, in 2014 the family of Mr. Vincent Lambert sought the decision of the ECtHR regarding the discontinuity of the artificial nutrition and hydration (application no. 46043/14) (e.g., see Sect. 2.1.1.1.).

In Germany, the most important case-law regarding end-of-life decisions are the case-law of 1994 (BGH 1StR 357/94) and 2003 (BGH XII ZB 2/03) where the judicial decisions have emphasised the primacy of the patient's will. It should be noted that from the end of the 1890s the German courts have protected patient autonomy. Recently, the German jurisprudence has gone even beyond the traditional legal distinction of act and omission (BGH 2 StR 454/09). By taking into account that some ethicists have argued that there is no intrinsic moral difference between killing and letting die (Deutsch and Spickhoff 2008, Kuhse 1998, Perrett 1996, Boyle 1977 and Rachels 1975)[39] and the legal principle of unity of the legal system,[40] the Bundesgerichtshof has stated, by applying the theory of some scholars, that this distinction is not based on the external actions. The German High Court

[39]On the contrary: (Beauchamp 1989, Childress 1985, and Maguire 1984)

[40] The principle of unity of the legal system should be considered in both horizontal and vertical approaches. Therefore, rules between civil and criminal law should not contrast. Either should contrast constitutional norms with legal rules.

applies the legal reasoning coming by the interpretation of article 1 (human dignity) and article 2 (personal freedom) of the German Constitution. It should be underlined that in this ruling, the Court states more precisely that active euthanasia and any kind of act that short life are illegal.

In England, some of the most important case-law are Bland (Airedale NHS Trust v. Brand [1993] AC 789) and Re T ([1992] 4 All ER 649). In the case of Bland, the English court rejected the substituted judgment doctrine by highlighting the principle of patient's best interest. Traditionally, the English common law has recognized to the British Crown, under the so-called 'parens patriae jurisdiction', the power to protect incapable citizens (Butler v. Freeman, E. 1756. Amb. 301). According to the principle of the patient's best interest, doctors can withdraw medical treatment when it is not in the patient's best interest prolong his or her life with 'no affirmative benefit'. Moreover, in this case-law it was stated that withdrawing treatment – although it is a physical act – from a legal prospective should be considered as an omission. While there is no moral or logical difference between act and omission, the legal distinction exits since otherwise, doctors would never start a medical treatment because they could never withdraw it. Furthermore, in the Re T., the court has decided that it is unlawful to administer life-saving or life-prolonging treatment in disregard of an anticipatory refusal.

6.1. Withdrawing treatment from incompetent patients in Italy: the case of Eluana Englaro

In Italy, bioethical debates about end-of-life decision making has increased in the last decades. This is the result of new medical discoveries (e.g. see Sect. 1.1.), the establishment of the Italian National Bioethics Committee, decreased influence of the Roman Catholic Church within Italian society, the new interpretation of article 32 of the Italian Constitution and the importance given by the media to cases connected with refusal of medical treatment.

In 1990, a Prime Minister's Decree led to the establishment of the Italian National Bioethics Committee as an advisory body to the Government composed of experts in the medical, ethical and legal field. The debate about end-of-life decision-making started only in the last decade of the last century. Before this time the Roman Catholic Church, that condemning such decisions, has had a big influence in the Italian society (Griffith 2008).

Article 32 of the Italian Constitution recognizes the 'right to health' that grants patients the right to consent or even withhold medical treatment. The right to health is safeguarded as *"a fundamental right of the individual and as a collective interest"* and can be limited only *"under the provisions of the law".*

It is also important to highlight the role of the media's attention on the case of Eluana Englaro who was in a vegetative state for more than fifteen years and the controversy following the final decision of the Court of Cassation. Since article 32 of the Italian Constitution recognizes the 'right to health', patients have the right to withhold or withdraw medical treatments. As it was confirmed from the Italian Constitutional Court (C. Cort. 26 June 2002), medical treatments have to protect not only the patients' health but also their dignity. Further, according to decision 307/1990 of Italian Constitution Court, this right can only be limited when the medical treatment protects not only the health of the single patient but also that of all the society. These are the cases of vaccination of a population or the cases of caregiving in the context of HIV. This limitation must be predicted and specified by the national law. In addition, any kind of assistance during death or euthanasia is considered illegal. In the case of assistance, physicians will be liable for homicide by request of the victim (article 579 Penal Code; P.C.) or, in case of incompetent patient, for intentional homicide (article 575 P.C.).

The complexity of legal and ethical issues concerning withdrawing treatment from an incompetent patient arises from the need to reconstruct the patient's will. The majority of lawyers believe that withdrawing treatment cannot be punished because despite the facts being similar to those of homicide by request of the victim (article 579 P.C.), there is the exculpation

act of fulfilment of duty (article 51 P.C.) (Canestrari 2003). However, a part of the legal community argues that humans do not have the moral right to die and therefore in case of incompetent patient, even if the patient has, during some point of his life given consent, there is the necessity to save patient's life (article 54 P.C.). In these cases the doctor is neither liable for kidnapping nor duress (articles 605, 610 and 613 of P.C.) (Iadecola 2003).

In Italy, the most famous case of withdrawing treatment from an incompetent patient is that of Eluana Englaro (25 November 1970 – 9 February 2009) from Lecco, who following a car accident, entered into a vegetative state on the 18 January 1992. The case of Englaro is also similar to that of Quilan in the USA. In 1999, Mr. Beppino Englaro asked for the first time the Tribunal of Lecco to discontinue hydration and nutrition supplying. The Tribunal of Lecco (1 March 1999) and then the Court of Appeal of Milan (31 December 1999) dismissed the case because of the absence of any legislation regarding withdrawing treatment from an incompetent patient. According to the judges article 2 of the Italian Constitution gives absolute and imperative protection of the right to life.

The Court of Cassation (10 April 2005 – ordinance) dismissed the case in 2005 based on the absence of a support guardian (*amministratore di sostegno*) (e.g., see Sect. 3.4) to confirm withdrawing treatment as the patient's own decision. Even after Franca Alessio was appointed as a support guardian, the Tribunal of Lecce declined Mr. Englaro's second request to stop life-sustaining treatment based on the fact that an incompetent patient lacks the right to reject medical treatment. Moreover, according to this ruling, supplied hydration and nutrition is not a medical treatment but basic care (Trib. Lecco 20 December 2005).

The Court of Appeal of Milan (16 December 2006) reversed the Tribunal's ruling by declaring that everyone has the right to reject medical treatment, but in this concrete case, the evidence was insufficient to clearly indicate that Ms. Eluana Englaro would have wanted to terminate her medically supplied nutrition and hydration. Mr. Beppino Englaro continued

his legal battle and on 16 October 2007 the Court of Cassation decided that judges can authorize the removal of life-sustaining treatment for patients who have been declared incompetent when two conditions are met: (1) it is clear that the patient is in a persistent vegetative state and (2) it can be determined by clear and convincing evidence, from the patient's representative, that the patient would not wish to be kept alive through artificial means, based on knowledge of the patient's lifestyle, personality and conviction. The same legal reasoning has been recently adopted by the Italian Council of State in its ruling of 2 September 2014, no. 4460.

The Court of Cassation did not enter into the medical or legal definition of persistent or permanent vegetative state, in addition to not giving a definition of medical futility. According to the Multi-society Task Force on PVS, persistent vegetative state is a result of a patient's vegetative state of one month after acute traumatic or non-traumatic brain injury, which concludes in a permanent state if the patient has been vegetative for one year (Ashwal 1994). Also, the English case-law of Bland ([1993] 1 All ER 821 at 850, (1993) 12 BMLR 64 at 95) confirms that the irreversible vegetative state one year later the injury. In addition, in the first six months of persistent vegetative state, every effort should be made at rehabilitation. In the case-law of Eluana Englaro, the Court did not have doubts that she was in a permanent vegetative case because she has been in that state for several years.

The judges did not give a definition of futile treatment because this would have raised several problems. Within this category, there are three types of futility: 'physiological futility', 'quantitative futility' and 'evaluative futility' (Campbell 2012). While the first classification of futility describes situations without any physical benefit, the other two raise ethical problems. The so-called 'quantitative futility' defines a really low probability of medical benefits; and the case of 'evaluative futility' is even more complex. In this case, the medical treatment could achieve benefits for the patient's health, but there is disagreement if these benefits would also contribute to the patient's wellbeing.

Therefore, the two main requisites to be fulfilled were the condition of vegetative state and the reconstruction of the patient's past wishes. Without thorough consideration, the court stated that "artificial nutrition and hydration through nasogastric tube constitutes medical treatment". The main problem in this case-law was to understand the patient's desire and the role of ADs in the Italian legal system. ADs play down the distinction between basic and medical treatment *or* that between proportional and excessive medical invasion (Lecaldano 2005). It should further be noted, that the concept of 'actual wish' should not be chronologically limited to the nearest future, but it should be considered as the last wish of the patient (Giunta 1991). Additionally, ADs cannot be considered as part of the concepts of 'right to die' or euthanasia (Balestra 1992). This is confirmed by empirical evidence from the Netherlands. There, euthanasia is legal and there exist two different types of advance directives: one for the medical treatment that the person would like or would not like to have in case of incompetence which can be considered as part of informed consent and the other concerning euthanasia (Vezzoni 2005). The same results come from the examination of the legal situation in Belgium. While advance directives are legally binding and not limited in time, advance directives that request euthanasia shall be only taken into consideration if they were written in the last five years.

The role of advance directives has been recognized by the Italian National Bioethics Committee on February 1992 and included in the Italian Medical Ethics Code (e.g., see Sect. 3.1.). According to advice given from the Italian National Bioethics Committee (2003), even in cases of planning of medical treatment from a patient who is suffering from a chronic illness, advance directives are not reliable. According to this advice, advance directives cannot be considered as a blinding force. The doctor has to take into account the patient's wishes, but he is not obliged to follow them.

After examining all the facts, the Court of Appeal of Milan (9 July 2008) accepted Mr. Beppino Englaro's request to discontinue artificially supplied hydration and nutrition. It should be mentioned that the final part of the

ruling was written with the help of a palliative care expert. This expert prescribed how the withdrawal of treatment had to be carried out in practice. This fact shows the strong interconnection between medicine, ethics and law in end-of-life decisions (e.g., see Sect. 2.5.).

In its ruling, the Court of Appeals also reminded the two well-known European law-cases involving judicial permission for withdrawing ANH from PVS patients: *Hervé Pierra* (France) and *Tony Bland* (United Kingdom). In addition to them, the Italian court could have referred to the cases of Kristina in Norway, and *Schiavo* in the United States (In re Schiavo, 90-2908GD-003).

Indeed, the *Englaro* case is very similar to that of *Schiavo*. Both of them were in a vegetative state for several years – Englaro for 17 years and Schiavo for 15 years – and both of them were kept alive through ANH. Moreover, in both cases, the legal proceedings were long and the courts issued several rulings. In addition, in both cases the governments reacted by passing legal norms to stop the execution of the courts' decisions to withdraw ANH. Furthermore, the Supreme Court of Florida and the Italian Constitutional Court were involved: both courts had to interpret the principle of separate powers within the State.

However, while in USA, all the rulings were in harmony, in Italy different courts expressed different positions. Moreover, while in *Schiavo* the patient's husband had a different opinion than his wife's family's, in *Englaro*, all of the patient's friends as well as her father shared the same idea: Eluana Englaro would not have wanted to live in that condition. Furthermore, while Terri Schiavo died 14 days after the withdrawal of ANH, Eluana Englaro died only 87 hours after the withdrawal of ANH. It should be noted that the case of Englaro appears to be the first documented death occurring after an unexpectedly short time following the withdrawal of ANH (Moreschi et al. 2013).

Following that, political reactions were immediate. The Italian Parliament accused the Cassation in front of the Constitutional Court for violating the principle of separation between powers recognised from the

combination of articles 70, 101, section 2, and 102, section 1 of the Italian Constitution. As is well known, in civil law countries, the courts should interpret and not create law. Meanwhile, the Constitutional Court (8 October 2008, no. 334 – Ordinance) defended the decision of the Court of Cassation as being an alternative logic-legal interpretation and not an attack on the Italian law. As a reaction of this ruling, on 6 February 2009, the Italian Council of Ministers approved a decree-law (decree-law no. 36), which is a law approved from the government in extraordinary cases of necessity and urgency, with the goal of blocking the withdrawal of artificial nutrition to Eluana Engaro.

This decree-law was not signed from the Italian President on the basis that it did not have the character of an extraordinary case of necessity and urgency needed from article 77 of the Italian Constitution. Furthermore, at the time, a bill to regulate artificial nutrition and hydration was being discussed. In addition, this law was a 'specific' law to interrupt the effect of the Cassation's decision with respect to Eluana Englaro. The result was an institutional crisis, which was overcome only when the Prime Minister decided to change the decree-law into a bill, bill 2350, which was immediately approved by the Italian Senate on March 2009, but which the Chamber of Deputies revised it on July 2011 (e.g., see Chap. 3).

In the middle of this political debate some associations asked the ECtHR to intervene since according to them there had been a violation of articles 2, 3 and 6, section 1 of the ECHR. The ECtHR stated that since these parties were not part of the original legal proceeding in Italy and since there was not a direct violation of their rights, the ECtHR could not take into consideration their applications (Application nos. 55185/08, 55483/08, 55516/08, 55519/08, 56010/08, 56278/08, 58420/08 and 58424/08).

Eluana Englaro passed away on 9 February 2009, after her percutaneous endoscopic gastrostomy tube was removed. The autopsy revealed that Eluana Englaro died without any evident signs of suffering.

Summary

The change of the approach towards end-of-life decision-making has been exposed: from a traditional one where the decision was made among the family members to a new approach where the significance of the national policy ruling ADs has been underlined.

The jurisprudence, the bioethical and the medical communities have pointed out the significance of ADs as instruments to enhance patient autonomy. Besides, the role of the legal proxy has been considered as a tool to resolve the problems regarding the implementation of directives expressed through written documents in concrete medical practice. Several examples from the national laws of England, Wales, Germany and France and the Irish Bill 2012 have been given to show the codification of this principle.

In addition, the evolution of patient autonomy has been investigated. While the individualist approach to autonomy rejects the influence of external factors, the relational autonomy accepts them, in addition to highlighting patient-physician communication.

Furthermore, the role of the jurisprudence to safeguard patient autonomy has been illustrated through the study of concrete case-law. As it is well-known, the process of the promulgation of a law is slower compared to the transformation of the society. This is a direct result of the fact that in end-of-life decisions the public discussion is continues and national legislators have difficulties to rule. But, on the other side, judges have an obligation to rule. It derives that national judges, by making an extensive interpretation of fundamental human rights, have substituted national parliaments by ruling in single case-law.

Concluding, in the last decades, there has been a transformation of the approach towards end-of-life decisions. This has influenced the conceptualization of patient autonomy through individualistic or relational approaches. Since the process of the promulgation of a law is slower compared to the transformation of the society, judges have assumed an

important role by “creating” laws, also in countries that are part of the civil law system.

References:

Alvrecht Gary L. and Patrick J. Devlieger, "The Disability Paradox: High Quality of life against all odds." *Social Science & Medicine* 48, no. 8 (1999): 977-988.

Ashcroft, Richard. "Death Policy in the United Kingdom." In *End-of-life Decision Making: a cross-National Study*, edited by Robert H. Blank and Janna C. Merrick, 197-218. Cambridge: MIT Press, 2005.

Ashley, Viv. "Philosophical models of personal autonomy (version 5)." University of Essex: Essex Autonomy Project (2013).

Ashwal, Stephen and others. "Medical aspects of the persistent vegetative state." *New England Journal of Medicine* 330, no. 21 (1994): 1499-1508.

Atkinson, Atkinson M. *Advance Directives in Mental Health: Theory, Practice and Ethics.* London: Kingsley Publishers, 2007.

Baier, Annette. *Postures of the Mind: Essays on Mind and Morals.* Minneapolis: University of Minnesota Press, 1985.

Balestra, Luigi. "Efficacia del testamento biologico e ruolo del medico", In *Il testamento biologico: riflessioni di dieci giuristi* edited by Fondazione Veronesi, 89-106. Milano: Giuffré, 2010.

Beauchamp, Tom L. and James F. Childress. *Principles of Biomedical Ethics*. New York: Oxford University Press, 1979.

Beauchamp, Tom L. "A Reply to Rachels on Active and Passive Euthanasia." In *Contemporary Issues in Bioethics*, edited by Beauchamp Tom L. and LeRoy Walters, 248-255. Belmont: Wadsworth Publishing Company, 1989.

Benbenishty, Julie and others. "Nurse involvement in end-of-life decision making: the Ethicus Study." *Intensive Care Medicine* 32, no. 1 (2006): 129-132.

Ben-Ishai, Elizabeth. *Fostering Autonomy: A Theory of Citizenship, the State and Social Service Delivery.* University Park, PA: Penn State University Press, 2012.

Berger, Jeffrey T. and Deborah Majerovitz. "Stability of Preferences for treatment among Nursing Home Residents." *The Gerontologist* 38, no. 2 (1998): 217–223.

Bilsen, Johan and others. "Drugs used to alleviate symptoms with life shortening as a possible side effect: end-of-life care in six European countries." *Journal of Pain and Symptom Management* 31, no. 2 (2006): 111–121.

Biggs, Hazel. "I don't want to be a burden! A feminist reflects on women's experiences of death and dying." In *Feminist Perspectives on Health Care Law,* edited by Sheldon Sally, 279–295. London: Cavendish Publishing Ltd., 1998.

Blustein, Jeffrey. "Choosing for others as continuing a life story: The problem of personal identity revisited." *The Journal of Law, Medicine & Ethics* 27, no. 1 (1999): 20-31.

Boyle, Joseph M. "On Killing and Letting Die." *The New Scholasticism* 51, no. 4 (1977): 433-452.

Bramstedt, Katrina A. "Questioning the decision-making capacity of surrogates." *Internal Medicine Journal* 33, no. 56 (2003): 257–259.

Braun, Ursula K. and others. "Reconceptualizing the Experience of Surrogate Decision Making: Reports vs Genuine Decisions." *Annals of Family Medicine* 7, no. 3 (2009): 249-253.

British Medical Association. *Statement on advance directives.* London: BMJ Publishing Group, 2007.

British Medical Association. *Withholding and Withdrawing Life-prolonging Medical Treatment Guidance for decision making*. Oxford: Blackwell Publishing, 2007.

British Medical Assossication. *Advanced Statements about Medical Treatment.* London: BMJ Publishing Group, 2007.

Brock, Dan W. "Medical Decisions at the End of Life." In *A Companion to Bioethics*, edited by Kuhse, Helga and Peter Singer, 263-273. Oxford: Wiley-Blackwell, 2009.

Brody, Howard. *Stories of Sickness.* Oxford: Oxford University Press, 2003.

Broom, Alex and Emma Kirby "The end of life and the family: hospice patients' views on dying as relational." *Sociology of Health and Illness* 35, no. 4 (2013): 499-513.

Buchanan, Allen and Dan W. Brock. *Deciding for Others: The Ethics of Surrogate Decision Making*. Cambridge: Cambridge University Press, 1990.

Buiting, Hilde M. and others. "Forgoing artificial nutrition or hydration in patients nearing death in six European countries." *Journal of Pain and Symptom Management* 34, no. 3 (2007): 305-314.

Bundesärztekammer, Zentrale Ethikkommission bei der Bundesärztekammer. "Empfehlungen der Bundesärztekammer und der Zentralen Ethikkommission bei der Bundesärztekammer zum Umgang mit Vorsorgevollmacht und Patientenverf ügung in der ärztlichen Praxis." http://www.bundesaerztekammer.de/downloads/Empfehlungen_BAeKZEKO_Vorsorgevollmacht_Patientenverfuegung_19082013l.pdf.

Bülow, Hans H. and others. "Are religion and religiosity important to end-of-life decisions and patient autonomy in the ICU? The Ethicatt study." *Intensive Care Medicine* 38, no.7 (2012): 1126–1133.

Canestrari, Stefano. "Le diverse tipologie di eutanasia: una legislazione possibile." *Rivista Italiana di Medicina Legale* 25, no. 5 (2003): 751 - 775.

Campbell, Margaret L. *Case Studies in Palliative and End-of-life Care*. Detroit: John Wiley & Sons, 2012.

Carmel, Sara and Elizabeth J. Mutran. "Stability of Elderly persons' expressed preferences regarding the use of Life-Sustaining Treatments." *Social Science & Medicine* 49, no. 3 (1999): 303-311.

Carrion, Iraida V. and others. "Advance care planning among Colombian, Mexican, and Puerto Rican women with a cancer diagnosis." *Supportive Care in Cancer : Official Journal of the Multinational Association of Supportive Care in Cancer* 21, no. 5 (2013): 1233-1239.

Childress, James F. "Love and justice in Christian biomedical ethics." In *Theology and Bioethics: Exploring the Foundations and Frontiers* edited by Earl Shelp 225-243. Boston: D. Reidel, 1985.

Code Lorraine. *What Can She Know?: Feminist Theory and the Construction of Knowledge.* Ithaca: Cornell University Press, 1991.

Cohen, Joachim and others. "Influence of physicians' life stances on attitudes to end-of-life decisions and actual end-of-life decision-making in six countries." *Journal of Medical Ethics* 34, no.4 (2008): 247-253.

Corrigan, Patrick. "How Stigma Interferes with Mental Health Care." *American Psychologist* 59, (2004): 614–625.

Costantini, Massimo and others. "Cancer trajectories at the end of life: is there an effect of age and gender?" *BMC Cancer* 2, no. 8 (2008): 127.

Council of Europe, Explanatory Report Recommendation CM/Rec (2009) 11.

Daveson, Barbara A. and others. "To be involved or not to be involved: a survey of public preferences for self-involvement in decision-making involving mental capacity (competency) within Europe." *Palliative Medicine* 27, no. 5 (2013): 418-427.

De Boer Marike E. and others. "Advance Directives in Dementia: Issues of Validity and Effectiveness." *International Psychogeriatrics* 22, no. 2 (2010): 201-208.

Degner Lesley F. and others. "The Control Preferences Scale." *The Canadian Journal of Nursing Research = Revue Canadienne de Recherche en Sciences Infirmières* 29, no. 3 (1997): 21–43.

Deutsch, Erwin and Andreas Spickhoff. *Medizinrecht: Arztrecht, Arzneimittelrecht, Medizinprodukterecht und Transfusionsrecht*. Berlin: Springer-Verlag, 2008.

Devettere, Raymond J. *Practical decision making in health care ethics: cases and concepts*. Washington: Georgetown University Press, 2010.

Dickenson, Donna L. "Cross-cultural issues in European bioethics." *Bioethics* 13, no. 3-4 (1999): 249–255.

Ditto, Peter H. and others "Stability of older adults' preferences for life-sustaining medical treatment." *Health psychology : Official Journal of the*

Division of Health Psychology, American Psychological Association 22, no. 6 (2003): 605–615.

Ditto, Peter H. and others. "Context changes choices: a prospective study of the effects of hospitalization on life-sustaining treatment preferences." *Medical Decision Making : an International Journal of the Society for Medical Decision Making* 26, no. 4 (2006): 313-322.

Dupont, Bernard M. "Refuse a 'Vincent Humbert law'." *Médecine Palliative* 4, no. 6 (2005): 309-311.

Entwistle, Vikki and others. "Supporting Patient Autonomy: The Importance of Clinician-patient Relationships." *Journal of General Internal Medicine* 25 (2010): 741–745.

Escher, Monica and others. "Impact of advance directives and a health care proxy on doctors' decisions: a randomized trial." *Journal of Pain and Symptom Management* 47, no. 1 (2014): 1-11.

Eurostat. "Mortality and life expectancy statistics." http://ec.europa.eu/eurostat/statistics-explained/index.php/Mortality_and_life_expectancy_statistics

Fagerlin, Angela and others. "The use of advance directives in end-of-life decision making." *American Behavioural Scientist* 46, no. 2 (2002) 268–283.

Forbes Gorgon and others. "Relationships between individualism-collectivism, gender, and direct or indirect aggression: a study in China, Poland, and the US." *Aggressive Behaviour* 35, no.1 (2009): 24-30.

Frankfurt, Harry. "Freedom of the Will and the Concept of the Person". In *The Inner Citadel: Essays on Individual Autonomy*, edited by Christman, John Philip, 63–76. New York: Oxford University Press, 1989.

Frolik, Lawrence A. "Is a Guardian the Alter Ego of the Ward?" *Stetson Law Review* 37, no. 53 (2007-2008): 53-86.

Gabl, Christoph and Ralf J. Jox. "Paternalism and autonomy--no contradiction." *Wiener medizinische Wochenschrift* 158, no. 23-24 (2007): 642-649.

García Ortega, Cesáreo and others. **"**Patient autonomy and information and clinical documentation-related rights within the context of Spanish Law 41/2002" *Revista Española de Salud Pública* 78, no. 4 (2004): 469-479.

General Medical Council. *Seeking Patients' Consent: the Ethical Considerations.* London, 1998.

General Medical Council. *Consent: Patients and doctors making decisions together*. London, 2008.

General Medical Council. *Treatment and care towards the end of life: Good practices in decision making.* London, 2010.

Giunta, Fausto. "Diritto di Morire e Diritto Penale. I termini di una Relazione Problematica." *Rivista Italiana di Diritto e Procedura Penale* 50, no. 1 (1997): 74 – 125.

Gomes Barbara and others. Local Preferences and Place of Death in Regions within England 2010. National end of life care Intelligence Network. London: Cicely Saunders Institute, 2011.

Griffith, John and others. *Euthanasia and the law in Europe*. Oxford: Hart Publishing, 2008.

Grande, Giuseppe and others. "Supporting lay carers in end of life care: current gaps and future priorities" *Palliative Medicine* 23, no. 4 (2009): 339–344.

Govi, Annamaria and others. "I Registri Comunali delle Dichiarazioni Anticipate di Trattamento: un'Analisi Critica." *Italian Journal of Legal Medicine* 1, no. 2 (2013): 61-71.

Hales, Sarah and others. "The quality of dying and death." *Archives of Internal Medicine* 168, no.9 (2008): 912–918.

Hawkins, Nikki A. and others. "Micromanaging death: process preferences, values, and goals in end-of-life medical decision making." *GERONTOLOGIST* 45, no. 1 (2005): 107-117.

Horn, Ruth. "Euthanasia and end-of-life practices in France and Germany. A comparative study." *Medicine, Health Care and Philosophy* 16, no. 2 (2013): 197-209.

Horn, Ruth "'I don't need my patients' opinion to withdraw treatment'': patient preferences at the end-of-life and physician attitudes towards advance directives in England and France'." *Medicine, Health care, and Philosophy* 17, no. 3 (2014): 425-435.

Hoppe, Nils and José Miola. *Medical law and medical ethics*. Cambridge: Cambridge University Press, 2014.

Howarth, Glennys. *Death & Dying: A Sociological Introduction.* Cambridge: Polity Press, 2007.

Hunt, Matthew R. and Carolyn Ells. "Partners towards autonomy: risky choices and relational autonomy in rehabilitation care" *Disability and Rehabilitation* 33, no. 1 (2011) 961-967.

Hunt, Sonja M. and others. *Measuring Health Status*. London: Croom Helm, 1986.

Iadecola, Gianfranco. "Note critiche in tema di "testamento biologico"." *Rivista Italiana di Medicina Legale* 24, no. 3-4 (2003): 473 – 483.

Italian National Council of Bioethics. *Dichiarazioni Anticipate di Trattamento.* 18 December 2003.

Italian National Council of Bioethics, "Dementia and Alzheimer's disease: ethical considerations", 20 June 2014.

Jelllinek, Georg. *Die sozialethische Bedeutung von Recht, Unrecht und Strafe.* Berlin: O. Häring, 1908.

Karel, Jennifer and others. “Assessment of Capacity to consent to Treatment: Challenges, the ‘ACCT’ Approach, Future Directions.” *Clinical Gerontologist* 31, no. 3 (2007): 37–66.

Karen, Steinhauser E. and others. “In Search of a Good Death: Observations of Patients, Families, and Providers” *Annals Internal Medicine* 132, no. 10 (2000): 825-832.

Kellehear, Allan. “Dying as a social relationship: a sociological review of debates on the determination of death.” *Social Science and Medicine* 66, no. 7 (2008): 1533–1544.

Kelly, David F. *Medical Care at the End of Life A Catholic Perspective*. Washington: Georgetown University Press, 2006.

Kemp, Peter and others. *Bioethics and Biolaw*. Copenhagen: Rhodos International Publishers, 2000.

Kemp, Peter and Jacob Dahl Rendtorff. “The Barcelona Declaration: Towards an integrated approach to basic ethical principles.” *Synthesis Philosophica* 46, no. 2 (2008): 239-251.

Kish Wallace, S., and others. “Influence of an Advance Directive on the Initiation of Life Support Technology in Critically Ill Cancer Patients.” *Critical Care Medicine* 29, no. 12 (2001): 2294–2298.

Knoppers, Bartha M. *Human Dignity and Genetic Heritage: A Study Paper*. Ottawa: Law Reform Commission of Canada, 1991.

Kuhse Helga. “Why Killing is not Always Worse – and Sometimes Better – Than Letting Die.” *Cambridge Quarterly of Healthcare Ethics* 7, no. 4 (1998): 371-374.

Lacroix Eve M. and Robert Mehnert. “The US National Library of Medicine in the 21st century: expanding collections, non traditional formats, new audiences.” *Health Information and Libraries Journal* 19, no. 3 (2002): 126–132.

Lavoie, Mireille and others. “The autonomy experience of patients in palliative care.” *Journal of Hospice & Palliative Nursing* 13, no. 1 (2011): 47–53.

Lecaldano, Eugenio. *Bioetica. Le scelte morali.* Bari-Roma: Laterza, 2005.

Lewis, Megan A. and Karen S. Rook “Social Control in Personal Relationships: Impact on Health Behaviors and Psychological Distress.” *Health Psychology* 18, no. 1 (1999): 63–71.

Locke, John. *The two treatises of government*. London: Everyman Paperback, 1993. [original work published 1690].

Löfmark, Rurik and others. “Physicians' experiences with end-of-life decision-making: survey in 6 European countries and Australia.” *BMC Medicine* 12, no. 6 (2008): 4.

Macintyre, Alasdair. *After Virtue: A Study in Moral Theory.* Notre Dame: University of Notre Dame Press, 2007.

Mackenzie, Catriona and Natalie Stoljar. *Relational Autonomy: Feminist Perspective on Autonomy, Agency, and the Social Self.* New York: Oxford University Press, 2000.

Maguire Daniel C. *Death by Choice.* Garden City: Doubleday & Company, Inc., 1984.

Manson Kenyon and Graeme Laurie. *Mason and McCall Smith's Law and Medical Ethics.* Oxford: Oxford University Press, 2011.

Menaca, Arantza and others. "End-of-life Care across Southern Europe: a Critical Review of Cultural Similarities and Differences between Italy, Spain and Portugal." *Critical Reviews in Oncology/Hematology* 82, no. 3 (2012): 387-401.

Mill, John S. *On liberty*. New York: Simon & Brown, 2012. [original work published 1865].

Moreschi, Carlo, and others. "The Eluana Englaro Case: cause of death after the withdrawal of artificial nutrition and hydration in a subject in a permanent vegetative state and with quadriplegia." *Forensic science international* 231, no. 1 (2013): e24-e29.

Neitzke, Gerald. "Umgang mit Patientenverfügungen in der Praxis." *Public Health Forum* 21, no. 3 (2013).

New York State Task Force on Life and the Law, *Life- Sustaining Treatment: Making Decisions and Appointing a Health Care Agent.* Albany: New York State Task Force on Life and the Law, 1987.

Nussbaum, Martha C. *Women and Human Development: The Capabilities Approach.* Cambridge: Cambridge University Press, 2000.

Olick, Robert S. "On the Scope and Limits of Advance Directives and Prospective Autonomy." In *Advance Directives*, edited by Peter Lack and others, 53-72. New York: Springer, 2014.

Oshana, Marina. *Personal autonomy in society.* Aldershot: Ashgate Press, 2006.

Owens, John. "Creating an Impersonal NHS? Personalization, Choice and the Erosion of Intimacy." *Health Expectations* 18, no. 1 (2015): 22-31

Owens, John and Alan Cribb, "Beyond Choice and Individualism: Understanding Autonomy for Public Health Ethics." *Public Health Ethics* 6, no. 3 (2013): 262-271.

Parfit, Derek. *Reasons and Persons*. Oxford: Oxford University Press, 1984.

Pecanac, Kristen E. and others "Respecting Choices and advance directives in a diverse community." *Journal of Palliative Medicine* 17, no. 3 (2014): 282-287.

Pereira, Ray. "Human handicap and self-determination: compassion and insensibility in the Vincent Humbert case." *História, Ciências, Saúde-Manguinhos* 14, no.1 (2007): 119-134.

Perrett, Royw W. "Killing, letting die and the bare difference argument." *Bioethics* 10, no. 2 (1996): 131-139.

Pope Thaddeus. "The best interest standard: both guide and limit to medical decision making on behalf of incapacitated patients." *The Journal of Clinical Ethics* 22, no. 2 (2011): 134-138.

Pope, Thaddeus M. "Legal Fundamentals of Surrogate Decision Making", *Chest* 141, no. 4 (2012): 1074–1081.

Prah Ruger, Jennifer. *Health and Social Justice.* Oxford: Oxford University Press, 2010.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *Deciding to Forego Life-Sustaining Treatment.* Washington: U.S. Government Printing Office, 1983.

Puchalski, Christina M. and others. "Patients who want their family and physician to make resuscitation decisions for them: observations from SUPPORT and HELP. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment. Hospitalized Elderly Longitudinal Project." *Journal of the American Geriatrics Society* 45, no. 5 Suppl (2000): S84-90.

Rabkin, Mitchell T. and others. "Orders not to resuscitate." *New England Journal of Medicine* 295, no.7 (1976): 364-366.

Rachels, James. "Active and passive euthanasia." *The New England Journal of Medicine* 292, no. 2, (1975):78-80.

Rendtorff, Jacob Dahl. "Basic ethical principles in European bioethics and biolaw: autonomy, dignity, integrity and vulnerability–towards a foundation of bioethics and biolaw." *Medicine, Health Care and Philosophy* 5, no. 3 (2002): 235-244.

Ricoeur, Paul. *Oneself as Another.* Chicago: University of Chicago Press, 1995.

Richardson, Henry S. "Specifying, balancing, and interpreting bioethical principles." In *Belmont Revisited: Ethical Principles for Research with Human Subjects*, edited by James F. Childress and others, 205–227. Washington, DC: Georgetown University Press, 2005.

Rini, Christine and others. "Interpersonal Influences on Patient's Surgical Decision Making: The Role of Close Others." *Journal of Behavioral Medicine* 34, no. 5 (2011): 396–407.

Rodríguez-Arias, David and others. "Advance directives and the family: French and American perspectives." *Clinical Ethics* 2, no. 3 (2007): 139–145.

Roger, Claire and others. "Practices of end-of-life decisions in 66 southern French ICUs 4 years after an official legal framework: A 1-day audit" *Anaesthesia, Critical Care and Pain Medicine* 34, no. 2 (2015): 73-77.

Rossi, Paolo G. and others. "Dying of cancer in Italy: impact on family and caregiver. The Italian Survey of Dying of Cancer." *Journal of Epidemiology and Community Health* 61, no. 6 (2007): 547-554.

Rubin, Allie N. and KatrinaA Bramstedt. "Examining the root cause of surrogate conflicts in the intensive care unit and general wards." *Monash Bioethics Review* 29, no. 1 (2010): 06.1-11.

Schicktanz, Silke. "Interpreting advance directives: ethical considerations of the interplay between personal and cultural identity." *Health Care Analysis : HCA : Journal of Health Philosophy and Policy* 17, no. 2 (2009): 158-71.

Schicktanz, Silke and others. "The cultural context of patient's autonomy and doctor's duty: passive euthanasia and advance directives in Germany and Israel." *Medicine, Health Care, and Philosophy* 13, no. 4 (2010): 363-369.

Seale, Clive. *Constructing Death: The Sociology of Dying and Bereavement.* Cambridge: Cambridge University Press, 1998.

Sehgal, Ashwini and others. "How strictly do dialysis patients want their advance directives followed?" *Journal of the American Geriatrics Society* 267, no. 1 (1992): 59-63.

Sen, Amartya. "Well-Being, Agency and Freedom: The Dewey Lectures 1984." *Journal of Philosophy* 82, no. 4 (1985): 169–221.

Shakespeare, Tom. *Disability research today: International perspectives.* London and New York: Routledge, 2015.

Shumaker, Sally A. and Richard A. Berzon. *The International Assessment of Health-related Quality of Life: Theory, Translation, Measurement and Analysis*. Oxford: Rapid Communications, 1995.

Siegel, Mark D. and others. "Psychiatric Illness in the next of Kin of Patients who die in the Intensive Care Unit." *Critical Care Medicine* 36, no. 6 (2008): 1722-1728.

Skilbeck Julie K. and Sheila Payne. "End of life care: a discursive analysis of specialist palliative care nursing Periodical." *Journal of Advanced Nursing* 51, no. 4 (2005): 325–334.

Spoto, Giuseppe. "Questione di Fine Vita tra modelli adottati in Europa, negli Stati Uniti e Proposte Interne." *Europa e diritto privato* 4 (2011) 1175 - 1196.

Sprung, Charles L. and others. "The importance of religious affiliation and culture on end-of-life decisions in European intensive care units." *Intensive Care Medicine* 33, no.10 (2007): 1732-1739.

Sprung, Charles L. and others. "Attitudes of European physicians, nurses, patients, and families regarding end-of-life decisions: the Ethicatt study." *Intensive Care Medicine* 33, no.1 (2007): 104–110.

Sprung, Charles L. and others. "Relieving suffering or intentionally hastening death: where do you draw the line?" *Critical Care Medicine* 36, no.1 (2008): 8-13.

Sprung, Charles L. and others. "Reasons, considerations, difficulties and documentation of end-of-life decisions in European intensive care units: the Ethicus Study." *Intensive Care Medicine* 24, no.2 (2008): 271-277.

Steinbock, Bonnie *The Oxford handbook of Bioethics.* Oxford: Oxford University Press, 2009.

Spinsanti, Sandro. "Obtaining consent from the family: a horizon for clinical ethics." *The Journal of Clinical Ethics* 3, no. 3 (1992): 188–192.

Swetz Keith M. and others. "Advance directives, advance care planning, and shared decision making: promoting synergy over exclusivity in contemporary context." *Journal of Pain and Symptom Manage* 47, no. 3 (2014): e1-3.

Teno, Joan M and others. "Do advance directives provide instructions that direct care? SUPPORT Investigators. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment." *Journal of the American Geriatrics Society* 45, no. 4 (1997): 508-512.

Teno, Joan M and others. "Role of Written Advance Directives in Decision Making. Insights from Qualitative and Quantitative Data." *Journal of General Internal Medicine* 13, no. 7 (1998): 439-446.

Teres, Daniel. "Trends from the United States with end of life decisions in the intensive care unit." *Intensive Care Medicine* 19, no. 6 (1993): 316-322.

Tibaldi Giuseppe and others. "From treatment adherence to advanced shared decision making: new professional strategies and attitudes in mental health care." *Current Clinical Pharmacology* 6, no. 2 (2011): 91-99.

Thom David H, and Babatunde Campbell. "Patient-physician trust: an exploratory study." *The Journal of Family Practice* 44, no. 2 (1997): 169-176.

Thom David H, and others. "Physician trust in the patient: development and validation of a new measure." *Annals of Family Medicine* 9, no. 2 (2011): 148-54.

Thomas Carl and others. "Place of death: preferences among cancer patients and their carers." *Social Science & Medicine* 58, no. 12 (2004): 2431–2444.

Toro, L. Blanco and others. "Perfil del cuidador principal del enfermo en situación terminal y análisis del riesgo de desarrollar duelo patológico." *Medicina Paliativa* 14, no. 3 (2007): 1-5.

Tsevat, Joel and others. "Health values of hospitalized patients 80 years or older. HELP Investigators. Hospitalized Elderly Longitudinal Project." *Journal of the American Medical Association* 279, no. 5 (1998): 371-375.

Van Delden, Johannes J. and others. "Do-not-resuscitate decisions in six European countries." *Critical Care Medicine* 34, no. 6 (2006): 1686-1690.

Van der Burg, Wibren. "Law and Bioethics." In *A companion to Bioethics,* edited by Kuhse Helga and Peter Singer. Oxford: Blackwell, 1998.

Venkatasalu, Munikumar R. and others. "Understanding the meaning of end-of-life discussions and related decisions among older South Asians living in East London: a qualitative inquiry." *British Medical Journal Supportive & Palliative Care* 1, no. 1 (2011): 79–80.

Vezzoni, Cristiano. *The legal status and social practice of treatment directives in the Netherlands*, Groningen: RUG (Rijksuniversiteit Groningen), 2005.

Vrakking, Astrid and others. "Comment on "Attitudes of European physicians, nurses, patients, and families regarding end-of-life decisions: the Ethicatt study" by Sprung et al." *Intensive Care Medicine* 33, no. 4 (2007): 747.

Walter, Jennifer K. and Lainie F. Ross. "Relational Autonomy: Moving Beyond the Limits of Isolated Individualism" *PEDIATRICS* 133, no. 1 (2014): S16-23.

Wiesemann, Claudia and Alfred Simon. *Patientenautonomie: Theoretische Grundlagen - Praktische Anwendungen.* Münster: Mentis-Verlag, 2013.

Wiesing, Urban and others. "A new law on advance directives in Germany." *Journal of Medical Ethics* 36, no. 12 (2010): 779–783.

Wilson, Fiona and others. "Autonomy and choice in palliative care: time for a new model?" Journal of Advanced Nursing 70, no. 5 (2014): 1020-1029.

Witting, Marsha N. and others. "Stability of preferences for end-of-life treatment after 3 years of follow-up: the Johns Hopkins Precursors Study." *Schistosomiasis* 168, no. 19 (2008): 2125-2130.

Woods Simon. *Death's Dominion: Ethics at the End of Life.* Maidenhead: Open University Press, 2007.

Wolf, Susan M. and others. "Sources of concern about the Patient Self-Determination Act." *New England Journal of Medicine* 325, no. 23 (1991): 1666–1671.

World Health Organisation. "European health report 2012 charting the way to well-being." http://www.euro.who.int/__data/assets/pdf_file/0004/197113/EHR2012-Eng.pdf

Worth, Allison and others. "Vulnerability and access to care for S. Asian Sikh and Muslim patients with life limiting illness in Scotland: a prospective longitudinal qualitative study." *BMJ : British medical journal / British Medical Association* 338, no. 3 (2009): b183.

Zelderloo, Luk. "Autonomy, belonging and interdependency." *International Journal of Integrated Care* 9 (Suppl) (2009): e79.

Zullo, Silvia. "Interruzione delle cure e morte cerebrale. Profili bioetici e filosofici." In *Bioetica e Biodiritto Problemi, casi e materiali.*, edited by Carla Faralli, 122 - 131. Torino: Giappicchelli Editore, 2010.

Chapter 2: Advance Directives in some Western European Countries

Abstract

The European bioethical background of end-of-life decisions is studied by examining some of the most important case-law of the European Court of Human Rights and some of the most important documents published by the Council of Europe. Moreover, national laws on advance directives in various Western European countries are analyzed.

The Recommendation CM/Rec (2009) 11 and the *Guide on the decision-making process regarding medical treatment in end-of-life situations* are analysed through an interdisciplinary approach. In particular, the Recommendation CM/Rec (2009) emphasizes the common European standards regarding end-of-life decisions and might be applied by the European Court of Human Rights, although it is considered a *soft-law.* Moreover, the *Guide on the decision-making process regarding medical treatment in end-of-life situations* stimulates the ethical debate among the public.

As it was demonstrated above, ethics and law are developed within a certain society. Different societies call attention to different moral values. Although a basic common European standard that safeguards patient autonomy exists, European policies differ from each other. Thus, national laws on advance directives in various Western European countries – such as Romance-speaking countries (Italy, France, Portugal, and Spain), English-speaking countries (Ireland, and United Kingdom of Great Britain and Northern Ireland), and German-speaking countries (Austria, Germany, and Switzerland) – are studied with the purpose of identifying the main moral principles protected by the national legislator.

After examining the similarities and differences between countries, the legislation of just four countries (Spain, France, England, and Germany) are analyzed in detail since the other countries in this survey have similar legal principles and/or a similar political approach. In particular, the Portuguese parliament of 2012 has used the Spanish law of November 2002 as a model. The Italian bill no. 2350 shares its political motivation with the previous version of the French law of 2005. The *Mental Capacity Act* recognizes similar principles with the other English-speaking countries. In German-speaking countries, national legislators have adopted the same political approach: they have modified their civil codes.

This contribution seeks to underline the common European background, and highlights differences and similarities between the policies examined.

1. The Council of Europe on the right to refuse medical treatment within the Council of Europe: the European Convention on Human Rights and Biomedicine of April 1997

The legal situation within the Council of Europe and in some of the Western European countries is studied. While the first part of it is dedicated to the situation within the Council of Europe – case-law studies, analysis of the Recommendation CM/Rec (2009) 11 and of the *Guide* of 2014 – in the second part the situation in Spain, France, England and Germany is examined.

The basic common European standard in end-of-life situations is demonstrated through the interpretation of the main case-laws decided by the European Court of Human Rights, and analysis of the Recommendation CM/Rec (2009) 11 and of the *Guide* of 2014. A particular attention is given to the case-law of Lambert (Application no. 46043/14) decided in June 2015. This case-law underlines the bioethical discussion regarding the withdrawal of ANH from an unconscious patient. Moreover, by giving concrete examples from the national laws, it is concluded that the European Court of Human Rights can apply the Recommendation CM/Rec(2009)11. This document, although it is considered a *soft-law*, shows the common European background in end-of-life decisions. In addition, in the examination of the *Guide*, it is highlighted the importance of the involvement of the patient's family and relatives in end-of-life decisions, in addition to the weightiness of the patient-physician communication.

In the second part, the different approaches in the national policies of ADs between Romance-speaking countries on one side, and on the other the English- and German-speaking countries, is delineated. This division is made based on the level of protection of patient autonomy and the role of physicians in end-of-life situations. Although all the policies analyzed safeguard patient autonomy, the Romance-speaking countries differ from the other groups (English- and German-speaking countries) since the national parliaments of the Romance-speaking countries also highlight the significance of the role of physicians.

The importance of the European Convention of Human Rights and Biomedicine[41] of April 1997 (hereafter, the *Convention*) is discussed. The *Convention* has implemented in the biomedical field the well-known set of ethical principles as suggested by US-American ethicists Beauchamp and Childress (1979), which has been established in general in the European Convention of Human Rights (ECHR)[42].

For several decades, the Council of Europe[43] has been concerning itself with problems regarding mankind as a result of advances in medicine and biology. It has always recognized the ambivalent nature of many of these advances. On one side, they could be used for a better life; on the other, some of these developments could potentially take a dangerous turn, as a result of a distortion of the original objectives. Therefore, with its new complexity and extensive ramifications, science presents a dark side or a bright side according to how it is used (Explanatory Report 164/1996, par. 2).

[41] The exact name of this convention is "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".

[42] In concrete, the principle of autonomy – established in article 8 of the ECHR – has been recognized in articles 5 and 6 of the Convention of Oviedo. The articles 2 and 3 of the ECHR, which recognized the principles of beneficence and non-maleficence, have been transferred in articles 2 and 4 of the "new" convention. In addition, the Convention of Oviedo has added the principle of justice (article 3), which was further developed in the Rec (2003) 24 of the Committee of Ministers of the Council of Europe on the organisation of palliative care.

[43] The Council of Europe is not an organ of the European Union. However, they do share the same values: human rights, democracy and the rule of law.

The preparatory work of the *Convention* started in 1992 and it was opened for signature on 4 April 1997 in Oviedo (Spain)[44]. This is the reason why this convention is known also as the 'Oviedo Convention'. According to its article 33, the Convention on Human Rights and Biomedicine entered into force in December 1999, after the fifth ratification, that of Spain. Until now, this treaty has been ratified by 29 members states[45].

The 'Oviedo Convention' comes from a general framework that was already agreed upon by the European bioethical community. This is why its preparatory work was concluded within few years[46]. This can be easily understood by reading its preamble, where other international conventions focussed in the protection of human rights have been mentioned. It follows

[44] During the drafting work the terms "bioethics" and "life sciences" were replaced with more specific terms. The term "bioethics" was replaced by the term "biomedicine" in order to show the connection between human dignity and integrity and the application of biology and medicine. Moreover, the phrase "life sciences" was substituted with a narrow concept of "application of biology and medicine", thereby excluding animal and plant biology insofar as they do not concern human medicine or biology.

[45] The 29 Member States that have ratified the Convention of Human Rights and Biomedicine are: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Greece, Hungary, Iceland, Latvia, Lithuania, Republic of Moldova, Montenegro, Norway, Portugal, Romania, San Marino, Serbia, Slovak Republic, Slovenia, Spain, Switzerland, "The former Yugoslav Republic of Macedonia", and Turkey.

[46] However, problems that could be not resolved in an international agreement (such as the legal statues of the human embryo and foetus) were addressed at the national level, but their regulation must be in accordance with the principles of this Convention.

that the *Convention* does not replace them but it can be used as a source of interpretation of the other international treaties.

The 'Oviedo Convention' is the first international legally binding comprehensive multilateral treaty addressing biomedical human rights issues. Although there existed other international documents, this is the first treaty where these rights have been developed and assembled in one single multilateral binding instrument entirely devoted to biomedical development[47]. For the first time in the international debate there is a link between human rights and biomedicine (Andorno 2005). Before it, the academia and professional regulators were accustomed to viewing medical ethics and international human rights law as distinct normative systems (Faunce 2005).

The 'Oviedo Convention' was born with the political intention to protect human rights. This is why it does not provide a precise and detailed solution to the most complex bioethical dilemmas such as the legal status of the human embryo, abortion, physician assisted suicide (PAS) or euthanasia. This is a

[47] Before 1997, there were international binding Treaties that protected specific areas of human rights such as the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950; the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981 or the Convention on the Rights of the Child of 20 November 1989. Furthermore, UNESCO or other international bodies have developed "soft law" agreements, such as Declarations and Recommendations. The most important of these international agreements, which do not have a legally-binding force, are the Declaration approved from UNESCO is the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948, and the Declaration of Helsinki "Ethical Principle for Medical Research involving Human Subjects".

political strategy which has the aim to find minimum European standards in the field of biomedicine that are accepted by all involved countries; without this strategy the *Convention* would have never been adopted.

Furthermore, this convention has shown the synergic relationship between human rights in general and the right to health, which are closely related to upon the enjoyment of other human rights. Although there are different social and cultural backgrounds, setting common standards in health legislation is indeed possible because patients' needs presuppose that "principles transcend local diversity" (Sokalska 2005). However, only with this convention, the codification of bio-law has acquired political status (Andorno 2002). This Convention has been considered as the «first steps towards the elaboration of an international biomedical law» (Andorno 2002).

The Convention on Human Rights and Biomedicine has adopted a pragmatic approach (Braun 2000). According to its article 27, States that have ratified it are not allowed to adopt a lower level of protection of human rights than those that have been recognized by the *Convention*. So, internal law of the parties shall conform to this treaty which may be achieved either by applying directly the Convention's provisions to domestic law or by enacting the necessary legislation to give effect to them. Moreover, in case of conflict between two international binding instruments, the principle that should be applied is not *lex posterior derogat legi priori* or *lex specialis derogat legi*

generali, but the convention should be applied which is more beneficial to the individual concerned[48].

The protection of human rights in this convention seems to be the best strategy for regulating biomedical research and practice at a transnational level. This is not surprising, since human rights are viewed in our fragmented world as the last expression of a universal ethics (Thomaska 2001), or as the lingua franca of international relations (Knowles 2001).

As it is well-known, medical discoveries interfere with our life every day. Therefore, this convention can be seen as *lex specialis* of the ECHR of 1950 (Application no. 8278/1978). The main aim of the 'Oviedo Convention' is that to use the principle of the ECHR to protect human rights in the field of biomedicine. Moreover, according to article 31, protocols may be concluded in

[48] It should be noted that the United Nations Secretary General has set up a United Nations Interagency Committee on Bioethics which is focused on ensuring harmony within international commitments.

specific fields[49]. So, this sort of up-dating of protection of human rights could come through the emanation of new protocols[50].

The benefits that new medical and biological discoveries should be affirmed on three level of protection: the individual, the society and the humankind in general. The interest of individuals is considered higher than the interest of the society or science (article 2). Only in precise situations and under strict conditions, the general interest can take priority (article 26, section 1).

The main contribution of this convention is the involvement of the public debate on the protection of human rights in the field of biomedicine. On a national level, there exist specific institutions, such as committees or councils on bioethics (ex. France, Denmark, Italy and Portugal) or different organisations, that usually focus on a specific bioethical topic (ex. UK) or the regulation of biomedical matters is decentralized (ex. Germany where the "Länder" organize public debates).

[49] Until now there are four protocols: Protocol on cloning, Protocol on Transplantation, Protocol on Bioethical Research, and Protocol on Genetic Testing for Health Purposes. From the preparatory work of this Convention, the role of protocols was underlined. The Recommendation No. 1160/1991 states that the convention in bioethics should contain general principles and additional protocols on specific areas. This was a political decision; this convention should have had legally binding force and should have been accepted from all the members of Council of Europe that have different socio-cultural-religious backgrounds.

[50] Article 29 of the European Convention on Human Rights and Biomedicine should be interpreted in the same prospective.

Public consultation in the field of biomedicine is considered fundamental because in this area decisions are taken on three different levels – individual, medical and legal – that are closely intertwined. Citizens decide for themselves; but to be able to do that, this does not have to be prohibited by the law and/or also by the medical community. If the law considers it as illegal or the medical community considers it as unethical, citizens will not be able to perform their decisions.

This is the reason why, in 1994, a preliminary draft version of the convention was open for public consultation. Additionally, article 28 codifies the importance of public discussion. However, in this international convention, public debate is not completely open[51].

The *Convention* is important because it avoids economic competition in biomedicine; providing legally binding norms for all States that ratified it, economic completion or 'medical tourism' in medicine and biology would be eluded because in all these countries there is the same level of human protection. In an economic crisis such as the one of recent years, economic competition in biomedicine could be a concrete risk.

[51] The Convention on Human rights and Biomedicine does not allow a public debate on some principle such as the prohibition of carrying out a medical operation without the free and informed consent of the person involved (article 5), the right of inform consent (article 10) or the prohibition of sex discrimination in genetic tests (article 12).

The absence of a direct legal action from individuals and the lack of sanctions are the major flaws of this convention. However, with the aim to cover these, article 29 recognizes the possibility of the ECtHR giving an interpretation of the present convention without direct reference to any specific proceedings pending in a court if this is asked from one of the governments of a party – after having informed the other parties – or from the Steering Committee on Bioethics.

Concluding, the European Convention on Human Rights and Biomedicine – which should be considered a pragmatic unfinished document – is the first international legally binding comprehensive multilateral treaty addressing human rights issues in biomedicine. It provides basic standards in the biomedical field that have been recognized by the ECtHR as fundamental. In addition, it avoids economic competition in biomedical research and stimulates public debate and political agreement in the field of biomedicine.

1.1. The interpretation of the right to refuse medical treatments by the European Court of Human Rights

The application by the ECtHR of Chapter II of the Convention on Human Rights and Biomedicine of April 1997, and in particular the right to refuse medical treatments, will be analyzed.

Chapter II of the Convention on Human Rights and Biomedicine of April 1997 is dedicated to informed consent. Within this chapter, article 9, which recognizes the importance of prospective autonomy, is important. This article states 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".* The Explanatory Report explains it preciously without giving several details regarding the meaning of the phrase "*shall be taken into account"*[52]. Therefore, the role of the ECtHR in filling the meaning of it has been considered fundamental. The same aim has the Recommendation CM/Rec (2009) 11 (e.g., see Sect. 2.1.2.) and the *Guide on the decision-making process regarding medical treatment in end-of-life situations* (e.g., see Sect. 2.1.3.).

Although the legal reasoning done by the ECtHR is based on the ECHR, this can perfectly be applied to the interpretation of Chapter II of the Convention for several reasons. Firstly, article 3 of the Charter of Fundamental Rights of the European Union 2000[53] has established patient autonomy as a fundamental requirement in the field of medicine.

[52] Par. 69 of the Explanatory Report of the Convention on Human Rights and Biomedicine states 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.

[53] Five EU-Members (Italy, Luxemburg, the Netherlands, Sweden and Poland) which signed the European Convention on Human Rights and Biomedicine on 4 April 1997 (except Poland that signed it on 7 May 1999) have not ratified it. The main reason of

Moreover, the European Convention on Human Rights and Biomedicine has been applied directly by the ECtHR[54], even against Member States of the Council of Europe who have not signed it (Application no. 53924/00) or against Member States that have signed but not ratified it (Application no. 8278/1978). Furthermore, the convention of Oviedo can be seen as *lex specialis* of the European Convention on Human Rights of 1950 (Application no. 8278/1978, Guide on the decision-making process regarding medical treatment in end-of-life situations of May 2014). In addition, the preamble of 'Oviedo Convention' cites the ECHR.

the absence of this ratification is: for the Netherlands, Sweden and Poland article 18 of this Convention; for Luxemburg, article 22; the Italian Parliament has approved the application of this convention, but the Government has not deposit the signature. However, no reasons why Italy did not deposit the instrument of ratification, were founded (Goffin 2008). It should be noted that the standards of the *Convention* will be applied to these countries for two main reasons. First of all, article 3 of the Charter of Fundamental Rights of the European Union of 2000, has the same legal value of the EU-Treaties, established informed consent (C. Cost. 24 October 2007, no. 348 and no. 349). Secondly, even if the *Convention* could be considered as a *soft-law*, the ECtHR has applied it in interpreting international treatments, even agreements that are not legally-binding (Application no. 14038/88).

[54]According to the "*Research Report: Bioethics and the case-law of the Court*", which is the most recent report published, the European Court of Human Rights has cited the European Convention on Human Rights and Biomedicine of April 1997 eleven times, eight times related to consent in medical treatments: Application no. 25781/94, par. 221; Application no. 61827/00, par. 58; Application no. 6339/05, par. 40; Application no. 74300/01; Application no. 52515/99, par. 56; Application nos. 45901/05 and 40146/06, par. 31; Application no. 27915/06, par. 35; Application no. 27617/04, par. 83; Application no. 18968/07, pars. 76-77.

Through a *non-originalist* interpretation[55], the ECtHR has always considered fundamental the protection of the ethical principle of patient autonomy and consequentially the right to self-determination. This protection comes from the combined interpretation of article 2 (*right to life*), article 3 (*freedom from torture and other inhuman or degrading treatment or punishment*) and especially of article 8 (*right to respect for private and family life*). Further, in case of refusing medical treatment for personal religious conviction, article 9 (*freedom of thought, conscience and religion*) must be applied (Application no. 302/02).

The right to decide about one's personal future in end-of-life decision making was recognized for the first time in the famous case of Pretty v. the United Kingdom, where the court states that the imposition of medical treatment without consent would interfere with a person's physical integrity in a manner capable of engaging the rights protected by article 8 (Application no. 2346/02, par. 63).

The term 'private life' used in article 8 of the ECHR is a broad concept; encompassing, *inter alia*, the right to personal autonomy and personal development (Application no. 44599/98, par. 47) or a person's physical and psychological integrity (Application no. 5410/03, par. 107). A patient's

[55] The *non-originalist* interpretation means that these are rights which are not expressly mentioned in the text but which, it is proposed, should nevertheless be 'read into' it. According to them, the protection of the right to self-determination should be not theoretical and illusory. (Letsas 2010)

decision is valid only in cases where the decision has been taken freely and with full understanding of the medical consequences (Application no. 31322/07) and the patient have been a competent adult (Application no. 45076/05). Otherwise, physicians should act according to the principle of the patient's best interest.

The State – in balancing the right to self-determination and the patient's best interest – has a positive obligation to protect personal autonomy in concrete situation (Application no. 11562/05). Recently, on 5 June 2015 the ECtHR has return to this problem (Application no. 46043/14). Any intervention against individual autonomy must be justified as being "in accordance with the law" and "necessary in a democratic society" for one or more of the legitimate aims listed therein (Application no. 27617/04, par. 183).

Medical intervention without the patient's consent is an infringement of the right to respect for private life (article 8 ECHR) (Applications nos. 45901/05, 40146/06, par. 75; and no. 61827/00, par. 75) and, in particular, the right to physical integrity (Applications no. 2346/02, par. 61 and 63; no. 61827/00, par. 70; no. 24209/94, par. 33; and no. 8978/80, par. 22). The violated right must be practical and effective and not theoretical or illusory (Application no. 27617/04, par 191; and no. 6289/73, par. 24). In addition, the infringement could be classified as torture (ex. article 3 ECHR) only in case there is a minimum level of severity, which depends case by case (Application no. 2627/09, par. 58; and no. 33394/96, par. 24).

Consent is not only necessary in cases of urgency. According to the ECtHR, there is no urgency if the medical situation was either deteriorating or was likely to deteriorate or when the patient was in any pain or discomfort (Application nos. 45901/05 and 40146/06, par 79). Moreover, a measure that is therapeutically necessary cannot in principle be regarded as inhuman and degrading (Application no. 54810/00, par. 112; and no. 52515/99, par. 82).

Concluding, patient autonomy and the right to self-determination regarding medical treatment has always been protected by the ECtHR through

a *non-originalist* interpretation of article 2 (*right to life*), article 3 (*freedom from torture and other inhuman or degrading treatment or punishment*) and especially of article 8 (*right to respect for private and family life*) of the ECHR. In addition, when deciding regarding the incapable patient, the ECtHR has declared that all the parties involved should make the decision based on the patient's wishes, by taking into consideration the patient's situation as a whole. The Cartesian dualism – defended by René Descartes (Howard 2003) and which established the dual existence of man (matter and mind) – does not find any place in these rulings. Therefore, the ECtHR has implemented the interpretation of article 1 of the Constitution of the WHO of 1946 which states that *"health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".*

1.1.1. Comments on the case-law of Vincent Lambert: the rulings of the *Conseil d'État* and of the European Court of Human Rights

The French case-law of Vincent Lambert has been commented. Although the main argument has been examined through a legal perspective, the concept of artificial nutrition and hydration (ANH) will be explained by applying medical and ethical approaches. The understanding of this concept through an interdisciplinary approach is fundamental since its medical classification influences the ethical and especially the legal reasonings.

After exposing the facts, the rulings coming from the *Conseil d'État* and from the ECtHR have been commented through a legal comparative approach. In particular, article 2 (*right to life*) of the ECHR of 1950, especially the State's positive obligation to protect citizen lives, will be analyzed. In the conclusions, the positions of the *Conseil d'État* (Applications no. 375081, 375090, 375091) and of the ECtHR (Application no. 46043/14) have been underlined.

Vincent Lambert was a tetraplegic patient at Châlons-en-Champagne Hospital and then, from June 2009 and on, in Berck-sur-Mer. In 2011 his

condition was characterised as minimally conscious and in 2014 as vegetative. As a result, he received ANH.

After the *collegial* proceeding established in article 37 of the French Code of Medical Ethics (e.g. see Sect. 2.3.2.), and by involving the patient's wife in it, Dr. Karigen decided in early 2013 to withdraw the patient's nutrition. This medical decision was overruled by the judge of the Châlons-en-Champagne Administrative Court, who granted the request to resume feeding and hydrating Lambert. Nevertheless, in December 2013, after a second *collegial* proceeding, Dr. Karigen decided again to withdraw Lambert's nutrition. The patient's family opposed it again by making a further urgent application to the Châlons-en-Champagne Administrative Court. The court, on January 2014, decided to suspend the withdrawal of Lambert's nutrition. One of the applicants and the Reims University Hospital appealed against that judgment to the urgent-applications judge of the *Conseil d'État,* which decided on 24 June 2014.

One day before the ruling of the *Conseil d'État*, the parents of Vincent Lambert (Mr Pierre Lambert and Mrs Viviane Lambert), his half-brother (Mr David Philippon) and his sister (Mrs Anne Tuarze) made an application to the ECtHR by relying on the violation of Article 2 (*right to life*) Article 3 (*prohibition of torture and of inhuman or degrading treatment*) Article 8 (*right to respect for private and family life*) and article 6, section 1 (*right to a fair hearing*). The ECtHR decided on 5 June 2015.

The main legal question that the *Conseil d'État* and then the ECtHR had to examine is if the artificially supplied nutrition and hydration to a patient in a vegetative state may be considered a medical treatment that can be withdrawn. Before commenting these rulings from a legal perspective, the medical classification of ANH and its consequences should be briefly studied by applying an interdisciplinary approach because its medical classification influences the legal consequences.

Within going to repeat parts of this thesis, it should be reminded that the European bioethical community classifies ANH as medical treatment or

general medical management. In addition, some official documents identify nutrition done through medical machines basic care (e.g. see Sect. 1.5.1. and 3.1.1.).[56] It follows that if ANH is considered basic care and there is the patient's request to withdraw it, physicians would be liable for homicide by request of the victim, which in several countries is considered as a criminal offence. Obviously, all scholars – even when they consider ANH a medical treatment – agree that the withdrawal of ANH without the patient's request will be considered an intentional homicide, except when continuing it is considered a futile or disproportionate treatment (Lecaldano 2005).

Starting now with the legal analysis of this ruling, the *Conseil d'État* stated that ANH fell into the category of treatment that could be withheld. The ruling clarified three main points. First of all, the law no. 2005-370 of 22 April 2005 applies to every patient – consumer of the French health care system – whether or not the patient is considered in on end-of-life situation.

[56] Italian Bill 2350 discussed by the Senate on 26 March 2009 and than from the Chamber of Deputies on 12 July 2011 and never passed into a law and re-proposed as a draft –bill by the Deputies Ms. Roccella and others on 26 March 2014; Italian Commission of Bioethics, "Alimentation and The nutrition and hydration for patients in a persistent vegetative state" (2005) http://www.palazzochigi.it/bioetica/testi/PEG.pdf; Technical and Scientific Commisison on "Vegetative state and minimum conscious state" established with the Italian Ministerial Decree of 12 September 2005 http://www.aduc.it/generale/files/allegati/cure_stato_vegetativo.pdf.

The *Conseil d'État* based its decision on the *originalist* interpretation[57] of the law no. 2005-370 of 22 April 2005 *Loi relative aux droits des malades et à la fin de vie,* the so-called 'Leonetti Act'. The law no. 2005-370[58], has modified the previous law no. 2002-303 of 4 March 2002 *Loi relative aux droits des malades et à la qualité du système de santé.* The former law stated that patients have the right to refuse ''a'' treatment without identifying what would have happen if the treatment was considered a life-sustaining treatment at the end of life. The law of 2005 gives citizens the right to refuse "every" kind of treatment. Therefore, since the 'Leonetti Act' states that all citizens have the right to refuse "every" kind of treatment there are no reasons why these rules should not be applied to the case of withdrawing ANH.

Secondly, treatment can be withdrawn in case of unreasonable obstinacy, interpreted as a treatment that is futile or disproportionate or has "no other effect than to sustain life artificially". Thirdly, it should be noted that although the patient is in a minimally conscious state or in vegetative state –

[57] *Originalist* theories attempt to link interpretation to the time when the law was enacted. This style of interpretation brings certainty into law. Within *originalist* theories there are two different groups: *textualism*. which focusses on the meaning of words and *intentionalism*, which emphasis the drafting history of the bill (Letsas 2010).

[58] It should be noted that the French law of 2005, *Loi relative aux droits des malades et à la fin de vie* of 22 April 2005, has been modified on March 2015, by the *Loi créant de nouveaux droits en faveur des malades et des personnes en fin de vie*. It seems that the new law is more liberal because advance directives are presumed to be legally binding and not time-limited.

which means that the patient cannot exercise his own autonomy directly – it does not justify by itself that doctors should withdraw ANH. Physicians must take into consideration not only medical criteria, but also the patient's previous wishes and preferences. In case that there is no 'living will', the surrogate and the patient's family and relatives should be involved. Only where the patient's ADs are unknown, the principle in *dubio pro vida* should be applied.

Regarding the reconstruction of the patient's wishes, it should be noted that Vincent Lambert had not nominated a surrogate. Nonetheless, doctors involved his wife. French doctors correctly applied the rules established in the Public Health Code (article 1111-13 and article 1111-6 CSP) because the legal system should be seen as a whole. The previous version of article 1111-13[59] stated that in case of the absence of a surrogate, family should be involved. In addition, article 1111-6 CSP states that a surrogate can be a parent, a relative or a doctor. The statements of Mr. Lambert's wife were precise and had been confirmed by one of Mr. Lambert's brothers.

Before ruling, the *Conseil d'État* required not only the report by Dr. Karigen – as it is established in article 37 of the French Code of Medical Ethics – but also asked other public organs (such as from the National Medical Academy, the National Ethics Advisory Committee and the National Medical

[59] It should be noted that the new law of March 2015, *Loi créant de nouveaux droits en faveur des malades et des personnes en fin de vie*, has abrogated article 1111-13 CSP.

Council and Mr Leonetti, the rapporteur for the Act of 22 April 2005) to submit their reports. This decision confirms that the medical classification of ANH influences the ethical and legal reasoning. Moreover, the *Conseil d'État* had examined the case sitting as a full court, which was highly unusual in injunction proceedings. This shows the seriousness that the French judges have given this case-law.

On 24 June 2014, the *Conseil d'État* concluded that all the conditions imposed by the law no. 2005-370 of 22 April 2005 had been met and that the doctor's decision to withdraw the artificial nutrition and hydration was lawful.

The case-law of Lambert was brought in front of the ECtHR on 23 June 2014. The applications claimed that the withdrawal of ANH is a breach of the State's obligation to safeguard the lives of citizens (article 2). Moreover, the deprivation of nutrition and hydration might constitute a torture (article 3) and also infringe Vincent Lambert's physical integrity (article 8). Furthermore, the doctor who had taken the decision had not been impartial (article 6, section 1).

Before deciding the merit of this case-law, the ECtHR has made several preliminary thoughts. First the court highlighted that health has been protected as a fundamental human right. Moreover, the importance of advance directives (ADs) has been highlighted in several parliaments of the members of the Council of Europe. Also, the Council of Europe has underlined the common European standards regarding this issue in several documents such as the Convention on Human Rights and Biomedicine of April 1997 (article 9), the Recommendation CM/Rec (2009) 11 of December 2009 (e.g., see Sect. 2.1.2.) and the Guide on the decision-making process regarding medical treatment in end-of-life situations of May 2014 (e.g., see Sect. 2.1.3.).

The main arguments of the ruling of 5 June 2015 regard the interpretation of article 2 ECHR. Judges based their decision on the ground that article 2 of the ECHR establishes both negative and positive obligation to the State. The State must refrain from the "intentional" taking of life (negative

obligations), in addition to safeguard the lives of those within its jurisdiction (positive obligations). All parties agreed that there is a distinction between the intentionally taking of a life (PAS and euthanasia) and therapeutic abstention (withdrawing of medical treatment). Moreover, the government highlighted that the aim of the withdraw is not that to put an end to life, but to discontinue a form of treatment which was refused by the patient directly (through 'living will') or indirectly (through the application of the substitute judgment theory), *or* this treatment is considered – from a medical prospective – as an unreasonable obstinacy. Thus, the ECtHR stated that there is no violation of the State's negative obligation (par. 124).

Regarding the possibility of a violation of the State's positive obligation established in article 2 of the ECHR, it should be noted that this is not the first time that the ECtHR has dealt with this issue (e.g. see Sect. 2.1.). Analyzing the violation of the state's positive obligation established in article 2, the ECtHR stated that there is no general agreement among the member States of the Council of Europe about the withdrawal of ANH (par. 74).

The medical classification of ANH and its ethical and legal consequences are still an important European bioethical topic. Recently, the Guide on the decision-making process regarding medical treatment in end-of-life situations published by the Committee on Bioethics of the Council of Europe on May 2014 has underlined the ethical and legal discussion regarding ANH. Although the Guide takes any official position regarding this topic, it states that this technique implies choices concerning medical procedures and devices (perfusion, feeding tubes). This is an important statement because since medical procedures and devices are involved, it follows that this 'medical preceding' cannot be classified – under a medical approach – as basic care.

While there is no general bioethical agreement regarding the classification of ANH (e.g., see Sect. 3.1.1.), different European policies ruling ANH highlight different moral values, which has led to diverse legal rules. For instance, the French, Italian and English legislators have *ad hoc* rules regarding this issue. In France, ANH will be withdrawn – after applying the

collegial proceeding established in article 37 of the Code of Medical Ethics – if the treatment has no effect other than the artificial maintenance of life (article 1111-5-1 CSP). In Italy, ANH must be maintained until the end of life, except in cases where they are no longer efficacious in providing the patient with the nutritional elements necessary for the essential physiological functions of the body. Moreover, ANH cannot be withdrawn through ADs (article 3, section 3 Bill 2350 repeated in the same form by the proposal-bill 2229 of 26 March 2014). In England and Wales, life-sustaining treatment – and therefore also ANH – can be withdrawn through ADs if it is stated in writing and signed by the *donor* or by somebody else in the donor's presence or under his directives (article 25 MCA).

But, all the member states of the Council of Europe agree on the importance of the patient's wishes in the decision-making process does exist (par. 147). Within them, different policies have been applied. For instance, in Western Europe, all the English-, German-, and Romance-speaking countries – except Ireland, Italy, and Northern Ireland – have enacted national *ad hoc* legislations on end-of-life decisions. All these parliaments have established that ADs are legally binding. Nevertheless, although all these countries emphasize the importance of the patient's right to self-determination, in Romance-speaking countries the ethical principles of beneficence and non-maleficence are legally acknowledged as well.

Since within the member states of the Council of Europe there is no agreement regarding the withdrawal of ANH, and different policies ruling ADs highlight different ethical values, in the ruling of Lambert, the ECtHR stated that States have a margin of appreciation regarding the means of striking a balance between the protection of the patients' right to life and the protection of their right to respect for their private life and their personal autonomy (par. 148). The ECtHR emphasizes that neither from article 2 nor from its case-law could be deducted that States must follow a specific procedure regarding the determination of this balance (par. 162).

While the protection of the patients' right to life had been achieved through the application of the principle in *dubio pro vida,* the safeguarding of the patients' right to respect for their private life and their personal autonomy has been established through the recognition of the importance of ADs, ruled by the law no. 2005-370 of 22 April 2005, and then modified on March 2015. In this concrete case, the French legislator has found the 'right' balance between these rights through the *ad hoc* collegial proceeding established in R. 4127-37 CSP and in article 37 of the French Code of Medical Ethics.

On 5 June 2015, the ECtHR stated that since there was no violation of article 2, the withdrawal of ANH cannot constitute torture (article 3). Moreover, the complaint raised by the applicants under Article 8 was absorbed by those raised by them under Article 2 (par. 184). In addition, the Court considered that the complaints raised by the applicants under Article 6 section 1, to the extent that they had not been dealt with already under Article 2, were manifestly ill-founded (par. 186).

Concluding, the medical classification of ANH influences the ethical and legal reasoning. This is why the *Conseil d'État* asked not only the report prepared by Dr. Karigen (the Mr. Lambrant's physician), but also invited the National Medical Academy, the National Ethics Advisory Committee and the National Medical Council and Mr Leonetti (the rapporteur for the Act of 22 April 2005) to submit general observations.

Ruling end-of-life situations is difficult. Therefore, the *Conseil d'État* had examined the case sitting as a full court, which was highly unusual in injunction proceedings. In addition, since in civil-law system *le juge est la bouche de la loi* ("the judge is the mouth of the law"), the French legislator on March 2015 had to modify the law of 2005 by ruling *ad hoc* the case of treatments that have no effect as the only artificial maintenance of life (article 1111-5-1 Public Health Code).

The ECtHR in its ruling on 5 June 2015 underlined the difference between the state's positive and negative obligations. Regarding the positive obligations, the court ruled that States have a margin of appreciation

regarding the means of striking a balance between the protection of the patients' right to life and the protection of their right to respect for their private life and their personal autonomy.

The French legislator has found the 'right' balance between these rights through the *ad hoc* collegial proceeding established in R. 4127-37 CSP and in article 37 of the French Code of Medical Ethics. Nevertheless, physicians should not focus on the abstract qualification of ANH as a futile treatment or not, but rather answer the question to what extent this treatment benefits a *specific* patient in a *specific* condition by taking into consideration the patient's wellbeing, a concept which is boarder than simply the aspect of physical health since it also includes the subjective idea of what constitutes health.

1.2. The Recommendation CM/Rec (2009) 11 of the Council of Europe

The Recommendation CM/Rec (2009) 11 adopted by the Committee of Ministers based on article 15 of the Statue of the Council of Europe, has been studied by giving some examples from national legislations from English-, German- and Romance-speaking countries. Although this recommendation is a

soft law[60], it is the first document on a European level, which provides guidance for member states in the reform of laws allowing provision to be made for future incapacity (Explanatory Report, par. 13).

This document is composed of a preamble and seventeen principles, which are divided into three main parts: scope of application, continuing powers of attorney, and advance directives. The second part is the longest for two main reasons. Firstly, several scholars have highlighted the importance of a legal proxy that interprets the patient's advance medical directives (e.g., see Sect. 1.4.1.). Secondly, the power of attorney is a contract that has been traditionally used in European legal systems. However, their use in health care decisions is new and some previous European legislation established the forfeiture of the right to represent the granter once the he or she has lost capacity and/or competency.[61] Therefore, specific rules are needed for providing their adaptation in the field of health.

Although the aim of this recommendation is much broader than health care – since it also covers decisions regarding welfare, and economic and financial matters – in this paragraph only those provisions that are relevant for health care issues, especially after the declaration of the patient's

[60] The term *soft law* refers to quasi-legal instruments that do not have any legally binding force. Their infringement does not imply any kind of sanction.

[61] Some examples are: in England, article 1 of the Enduring Powers of Attorney Act of 26 June 1985; in France, article 2003 Civil Code; in Italy, article 1728 Civil Code; in Portugal, article 1174 Civil Code; and in Spain, article 1732 Civil Code.

incapacity, will be studied. For this reason, the paragraph 2.1.2.1. will be exclusively dedicated to the provisions regarding the power of attorney for health, welfare and other personal matters.

The goal of this recommendation is the promotion of self-determination (principle 1). This is not surprising, since the value of advance directives lies in the promotion of the ethical principle of patient autonomy and consequently the right to self-determination (e.g., see Chap. 1).

The term "incapacity" differs from the term "legal incapacity". "Incapacity" is limited to what might be termed "factual incapacity". These are the cases of a person in a coma or in a persistent vegetative state or a patient in severe dementia or a profound learning disability (formerly "mental handicap"). "Legal incapacity", on the other hand, is a sanction given by the national courts in case of a criminal offence or bankruptcy. It refers to the diminution by law of an adult's rights and status. Citizens with disabilities must never have such legal incapacity imposed upon them by reason of their disabilities[62].

In the preamble, different international and regional documents related to the protection of the rights of incapable adults have been mentioned[63]. In

[62] This principle has been established in Recommendation N° R(99)4 (principle 3) and in the United Nations' Convention on the Rights of Persons with Disabilities (article 12.2).

[63] In addition to the Convention on Human Rights and Biomedicine and to the Recommendation R(99)4, which will be analyzed into details, the Recommendation

particular, special attention has been given to the Convention on Human Rights and Biomedicine and to the Rec (99)4 of 23 February 1999[64]. The additional value of the Rec (2009) 11 compared to the Convention of Oviedo (article 9) is based on the fact that this document takes into consideration all kinds of advance medical treatments[65].

The recommendation of 2009 considers the Recommendation N° R(99)4 a "valuable and up-to-date international instrument" in this field. In fact, the working party "Incapable Adults"[66] had the task of complementing the

CM/Rec (2009) 11 mentions the United Nations' Convention on the Rights of Persons with Disabilities of 13 December 2006 (especially Article 12); the Hague Convention on the International Protection of Adults of 13 January 2000 (especially Articles 15, 16 and 38); Convention for the Protection of Human Rights and Fundamental Freedoms; and the Recommendation Rec(2006)5.

[64] This Recommendation is the result of the Group of Specialists on Incapable and Other Vulnerable Adults, later renamed the Group of Specialists on Incapable Adults, set up in 1995 after the 3rd European Conference on Family Law entitled "Family Law in the Future", held in Cadiz, Spain, in April 1995. The Recommendation N° R(99)4 has been applied by the European Court of Human Rights in three judgments: Application No. 54797/00, Application No. 44009/05 and Application No. 11223/04. Moreover, this Court has considered this Recommendation as a document that shows the common European standard in this area (Application No. 44009/05, par. 95).

[65] Article 9 states that "previously expressed wishes (….) shall be taken into account". Therefore, the Convention of Oviedo focuses only on advance medical directives, and nothing has been established regarding the nomination of the surrogate. In addition, the explanatory report of the Convention of Oviedo does not define what "shall be taken into account" means (e.g., see Sect. 2.1.).

[66] The Working Party "Incapable Adults" of the Council of Europe was set up in autumn 2006. It was comprised of international experts from legal practice who act independently of the governments. The main focus of this working party has been the

Recommendation N° R(99)4 by drawing up a new recommendation to deal with advance directives and continuing powers of attorney. This is why in only two years, the working party presented the first preliminary draft recommendation and a preliminary explanatory memorandum.

The main difference between these two documents regards their approach: the 1999 recommendation deals with measures of protection provided by competent *authorities* (i.e., courts) while the new instrument covers decisions made *privately* by the concerned persons themselves. Therefore, the Rec (99)4 deals with measures of protection provided by courts. In case of a nomination of a legal proxy by the court for incapable adults, the national parliaments have applied the "monistic" approach, – such as in German- and English-speaking countries, – or the "pluralistic" one, – such as in Romance-speaking countries. The Rec (2009) 11 deals with the figure of the surrogate[67]; it has nothing to do with cases where a person is capable and needs support to exercise his or her rights. This policy avoids judicial and administrative proceedings, is fasters and it further promotes the ethical principle of autonomy.

protection of adults who, for various reasons, are temporarily or permanently incapacitated to act without aid from others. Its last meeting took place in September 2008.

[67] Regarding the phrases used to indicate the 'surrogate' in English-, German- and Romance-speaking countries, please see note 29).

In this recommendation, the definition regarding advance directives has been defined in a narrow sense as "instructions given or wishes made" by the capable person (principle 2)[68]. This definition is similar – but not equal – to the term of "living wills" (e.g., see Sect. 1.4.). Therefore, the notion of advance directive is the one that is given in this recommendation. This is why the short expression ADs will not be used.

Differently from the part dedicated to the power of attorney, in part III health issues are mentioned first. This shows that advance directives, within the definition given above, have been well accepted by scholars mostly regarding health issues. These documents are always unilateral acts, which do not establish a contract with any other person. Physicians or surrogates[69] can interpret or ascertain them; however, this does not constitute a contract. Furthermore, these documents are effective only in case of the granter's incapacity.

[68] Please notice that in this thesis, it has been applied a broader definition of advance directives. For more information regarding it, please see Chap.1.3. The only exception to this rule occurs in this paragraph (Sect. 2.1.2.) with the aim to stay coherent with the Rec (2009) 11.

[69] Since advance directives are documents used to implement the patient–physician relationship, it follows that the final decision as to their execution lies with the physician in charge. Notwithstanding, the law can establish a direct exception. For instance, in Germany, the law explicitly states that the legal proxy (guardian or surrogate) must examine whether these determinations correspond to the current living and treatment situation (article 1901a, section 1 BGB).

States should decide to what extent advance directives should have binding force (principle 15)[70]. This includes the possibility to introduce professional assistance, which should be considered as a recommended or even compulsory step[71] or to establish a written form[72]. In addition, States should address the issue of situations that arise in the event of a substantial

[70] Currently all the English-, German- and Romance-speaking countries have established legally-binding force of advance directives. The old version of the French law of 2005 established an advisory force of advance directives. In Italy, all new proposals – expect proposals 2350 and 2229 – establish the legally-binding force of ADs. The proposals 13 (article 21, section 1), 1298 (article 3, section 2), and 2264 (article 2, section 4) state it directly; the other proposals establish it indirectly.

[71] In Austria: in case of legally-binding advance directives, the advice the physician is needed (14 law 8 May 2006, *Patientenverfügungs-Gesetz – PatVG*). In addition the citizen must sign the advance directive in front of the lawyer, a notary or a legally qualified employee of the patient groups (article 6); in England and Wales: the presence of a witness is needed (article 25, section 6, let. d); currently in France, nothing has been established, but in the following months the Council of the State will publish a degree with the condition of validity and confidentiality of advance directives (article 1111-11 CSP); in Portugal: in case of advance directives through the model of the National Register of Living Wills, the need of the employer of this public organ or of the Noter is needed; or in case of a handwritten living will the advice of a physician is necessary (article 3); in Spain, most Autonomous Communities' regulations establish several formal requirements. (Navarro-Michel 2005); in Italy, the proposals 2350 (article 3, section 1 and article 4, section 1) and 2229 (article 3, section 1 and article 4, section 1) establish the need of a medical advice. Instead, the proposal 443 establishes the need of the advice of a Noter and that of the physician (article 13); the proposal 1298 requires the presence of two witnesses (article 3, section 7); and the proposal 2264 states that the ADs should be written in front of the public employer of the Municipality Register of Advance Directives (article 2, section 3).

[72] Currently all the English-, German- and Romance-speaking countries have established a written form of 'living will' (e.g. see Sect. 2.2.).

change in circumstances[73]. This is a repetition of par. 21 of explanatory report of the Convention of Oviedo.

Moreover, principle 15 states that advance directives which do not have binding force should be treated as statements of wishes to be given due respect. The use of the term "due respect" is stronger than the phrase "shall be taken into consideration", used in article 9 of the Convention of Oviedo (Andorno 2010)[74]. Several State policies, although they do not directly recognize the legally-binding force of advance directives, use different expressions that suggest that advance directives are indeed legally binding.[75]

[73] While the Iberian Parliaments – in Portugal (article 5) and in Spain (article 11, section 3) – establish it in general, in Austria (article 10, section 1, nr. 1 of 8 May 2006, *Patientenverfügungs-Gesetz – PatVG*), in England and Wales (article 25, section 4 let c)), and in Italy [proposals 13 (article 21, section 1), 1432 (article 1, section 1, let. h)), 1298 (article 3, section 2), and 2264 (article 2, section 4)], advance decisions will not be applied in case that there has been a medical discovery or a change in the patient's pathology that if the patient had known them, would have changed his or her medical instructions. In France, this option could derive from the interpretation of the new article 1111-11 CSP, which states that these documents shall not be applied in cases that are manifestly inappropriate (article 1111-11 CSP). In Germany, this problem has been resolved by given to the legal proxy the power to examine whether these determinations correspond to the current living and treatment situation (article 1901a, section 1 BGB).

[74] However, it must be mentioned that the French version of this recommendation uses the same expression that appears in the Convention of Oviedo.

[75] For instance: in Italy [proposals 13 (article 21), 1298 (article 3, section 6), and 2264 (article 2, section 2)] through different expressions which has in common the use of the verb 'rispettare'; in France, the phrase used is 's'imposent au médecin' (new version of the article 1111-11, section 3 CSP); and in Switzerland, through the

Advance directives may be made in writing or may be expressed orally to family members, medical staff or others. The form of advance directives has been left to the decision of national parliaments (principle 16). States can establish that only certain types of advance directives have legally-binding force, and the other types have only advisory force, such as in Austria[76]; or States can establish that every types of expressed wishes have legally-binding force, such as in Germany (e.g., see Sect. 2.5.1.). If the advance directive regards health issues, State policy can take into consideration requiring from citizens that they acquire certain information from a physician, a lawyer or a Noter (e.g., see *supra* note 71). Moreover, the State can establish a national register regarding advance directives.[77]

expression 'die Ärztin oder der Arzt entspricht der Patientenverfügung' (article 372, section 2 ZGB).

[76] In Austria ADs can be legally-binding or not. In case of legally binding AD, the interested party must receive complete medical information by the physician and legal information by the Noter. In addition, this document is valid for five years; if not renewed with the same formalities, it will have only an advisory power. This document may be registered in the Austrian Chamber of Nataries.

[77] In Austria (article 284g ABGB); in England and Wales (article 13); in France (article 1111-6, section 1 CSP); in Ireland (article 50); in Portugal (article 14, section 1); in Switzerland (370, section 3 ZGB). In Germany, this possibility has been established directly only regarding 'living wills' (article 1901a, section1); in Spain, this has been recognized for all kind of 'prior wishes' (article 11, section4). The Scottish legislator has established several causes of termination of the power of attorney (article 25), but has not established directly the possibility of revocation. In Italy, the revocation has been established in all the proposals [Proposals 2350 (article 4, section 4), 5 (article 12), 13 (article 25), 443 (article 15), 1142 (article 13), 1298 (article 3, section 7), proposal 2229 (article 4, section 4), and 2264 (article 4,

An advance directive shall be revocable at any time[78] and without any formalities[79] (principle 17). This should be a direct consequence of their change of view (Explanatory Report, par. 185). Citizens must have the opportunity to revoke the advance directive even in cases when these documents are legally binding. The revocation can be done as long as the adult is still capable. If the document is already entered into a register, it is necessary to register the revocation.

1.2.1. Provisions regarding the power of attorney for health, welfare and other personal matters

Part II of the Recommendation CM/Rec (2009) 11, composed of principles 3 to 13, has been dedicated to continuing powers of attorney. This part reflects the trend in legislation towards giving priority to the establishment of private

section 4)], except proposal 1432. All these proposals establish the revocation regarding all kind of advance directives without distinguishing between 'living will' and 'surrogate will'.

[78] The countries that establish this principle are: in England and Wales (article 24, section 3); in France (article 1111-11, section 2 CSP); in Portugal (article 8, section 3); in Switzerland (371, section 3 ZGB); for the other states, *supra* note 77.

[79]The countries that establish this principle are: in England and Wales (article 24, section 4 and 5 and article 25, section 2, let c); in Italy (article 25 proposal 13); in Germany (article 1901a, section 1 BGB).

continuing powers of attorney over public measures of protection[80]. In other words, national legislators should consider the role of surrogate more important than that of the guardian[81].

The recommendation defines "continuing power of attorney" as "a mandate given by a capable adult with the purpose that it shall *remain* in force, or *enter* into force, in the event of the granter's incapacity" (principle 2.1). This definition incorporates several types of attorneys, not only powers of attorney that continue after the granter's incapacity, but also the powers of attorney which enter into force after granter's incapacity has been established[82].

While power of attorney for economic and financial matters could be utilized for both these types, the powers of attorney for health, welfare and

[80] This policy is in accordance with Principle 5 of Recommendation No. R (99) 4, which states that "no measure of protection should be established for an incapable adult unless the measure is necessary".

[81] Generally, this principle is presumed. However, in Ireland (article 22, section 2), in Italy [proposals 13 (article 20, section 1), 1298 (article 3, section 4), and 2264 (article 2, section 5)], in England (article 19, section 1), and in Switzerland (article 378, section 1 ZGB) this has been established directly. On the contrary, the new French law of March 2015 has established that in case of a public measure, it is the court that will decide if the person should be continued to be assisted by this person or by the surrogate the patient has nominated (article 1111-6, section 4 CSP). The same conclusion was derived in Scotland too (article 24, section 2).

[82] This difference has been shown even by the fact that the bankruptcy of the attorney will end economic powers, but not welfare powers. The same principle has been expressly recognized established in England and Wales (article 13, section 3), in Scotland (article 16, section 7) and in Ireland (article 49, section 5, let. c)).

other personal matters can be given only after the declaration of the granter's incapacity (Explanatory Report, par. 57 and 88). In case of continuing power designed to enter into force in the event of the granter's incapacity, States should consider how incapacity should be determined and what evidence should be required (principle 7).[83] According to the Guide on the decision-making process regarding medical treatment in end-of-life situations (p.16) (e.g. see Sect. 2.1.3.), the patient's incapacity should be assessed by an impartial expert. In addition, this proceeding should be documented.

In most States, a continuing power of attorney is unilateral at the time of granting and requires the acceptance from the attorney.[84] The granter should have the opportunity to nominate more than one surrogate[85]. Two or more surrogates may be the solution to undue concentration of power, or to reduce the risk of family dispute (Explanatory Report, par. 98). Usually, the attorney has to be an individual, natural person, but it might also be a legal

[83] In Italy [Proposals 2350 (article 3, section 5), 5 (article 10, section 2), 443 (article 14, section 2), 1142 (article 11, section 2), and proposal 2229 (article 3, section 5)] a medical team has been established to certify it. In England and Wales (article 3), in Ireland (article 3), and in Scotland (article 1, section 6) a definition of what constitutes incapacity has been given. On the contrary, the Portuguese Parliament has established what constitutes 'capacity' (article 4).

[84] In Italy, the proposals 2350 (article 6, section 1) and 2229 (article 6, section 1) require the sign of the surrogate. In England, article 25 establishes that the surrogate must sign his nomination in case of withdrawing life-prolonging treatment.

[85] England is the only country in our study to enshrine this possibility (article 10, section 4). The maximum number of LPAs is 5 (article 6 The Lasting Powers of Attorney, Enduring Powers of Attorney and Public Guardian Regulations).

person[86]. States can restrict this right by suggesting who can be nominated as a surrogate[87] or by establishing who cannot be a surrogate[88] (principle 4). In addition, the granter can establish some directives[89] or predict some exclusion[90]. Moreover, the granter must always have the opportunity to revoke this power (principle 6)[91].

A balance between the ethical principle of autonomy and the protection of life should be found. Therefore, States can introduce a system of certification, and/or registration and/or notification (principle 8)[92]. This is

[86] Switzerland is the only state where a legal person can be nominated as a surrogate (article 360 ZGB).

[87] For example, in France: article 1111-6 CSP states that a surrogate can be a parent, a relative or the attending physician.

[88] For example, in England article 10, section 1 states that the surrogate must be over 18 years old; further, section 7.10 of the Code of Practice of the Mental Capacity Act states that people working as a paid care workers (such as a care home manager) – with only few exceptions – shall not be appointed as an attorney; and in Portugal, article 11, section 2 states that surrogates must be fully competent, therefore, not a minor, *interdição* (interdict) or *inabilitação* (inability).

[89] This is in harmony with Principle 9 of the Recommendation No. R (99) 4.

[90] Any such exclusions should be kept to a minimum (Explanatory Report, par. 94).

[91] In Austria (article 284g ABGB); in England and Wales (article 13); in France (article 1111-6, section 1 CSP); in Ireland (article 50); in Portugal (article 14, section 1); in Switzerland (370, section 3 ZGB).

[92] In English-speaking countries [in England and Wales (article 58, section 1), in Ireland (article 48, section 1), and in Scotland (article 6, section 1)] the Public Guardian is responsible for establishing and maintaining a national register of surrogates. In Austria, the legally-binding advance directive should be registered in the Austrian Chamber of Notaries (282f ABGB). In Switzerland, the advance

necessary due the fact that – especially in case of continuing power designed to enter into force in the event of the granter's incapacity – the granter loses the control upon the attorney. In addition, several empirical studies have shown the disadvantages regarding the surrogate (e.g., see Sect. 1.3.1.). However, it must be noted that the granter has calculated this risk (Explanatory Report, par. 160) and has decided to nominate a surrogate (e.g., see Sect. 1.3.1.). The certification, registration or notification may constitute alternative solutions, or may supplement each other (Explanatory Report, par. 130).

Furthermore, States should protect the granter by establishing *ad hoc* norms in respect of resolving conflict of interest (principle 11) and supervision (principle 12) [93]. In these cases, national parliaments by taking

directives should be registered in the card of the insurance (article 371, section 2 ZGB). In France, the new law of March 2015 gives to the Council of State the duty to decide on the conservation of these documents (1111-11, section 4 CSP). In Germany, no national register has been established either for advance directive nor for the attorney. In Iberian countries – in Portugal (article 15, section 1) and in Spain (article 11, section 5) – national Ministries of Health are responsible for running the national register of ADs. The same has been established in Italy [proposal 2350 (article 8, section 1) and proposal 2229 (article 8)]; on the contrary, the proposal 443 gives this role to the National Chamber of Notaries (article 16) and the proposal 1298 demands this duty to the Commission for Control constituted in the Ministry of Health (article 7).

[93] For instance: in English-speaking countries this role has been given to the Public Guardian [in Ireland (article 56); in England and Wales (article 58), an in Scotland (article 9)]. In Italy, this role has been given to the physician's in charge [proposals 5 (article 9, section 1) and 1142 (article 10, section 1)] or to the Court of Guardianship [proposal 443 (article 11, section 1)].

into consideration the principle of self-determination should minimize the provision for judicial or other intervention (Explanatory Report, par. 167).

Concluding, the Rec (2009) 11 shows the common European standard in this area. In addition, it has influenced the other legislators that until 2009 have not passed legislation on advance directives. All the Parliaments in the English-, German- and Romance-speaking countries have recognized the significance of patient autonomy and the nomination of a surrogate. Within them, national parliaments in the English-speaking countries have established similar principles with this recommendation. In Scotland, the law is mainly focussed on the activities and the role of the legal proxies, such as *guardian* and the *continuing or welfare power of attorney*. Moreover, the new Irish Bill of 2013 is completely focused on the role and activities of the legal proxies, such as the *decision-making assistant*, the *co-decision-maker*, the *decision-making representative*, the *informal decision-maker*, and *the enduring power of attorney*. In England and in Wales (article 25, section 2, let. b)) and in the Irish bill 2012 (article 6, section 2, let. b)), the role of the surrogate has been highlighted by establishing that a previous 'living will' is not valid if the donor, after having written the 'living will', has created a lasting power of attorney which confers the authority on the donee to give or refuse consent to the treatment to which the advance decision relates. Therefore, although is a *soft-law*, the ECtHR could apply this recommendation as well.

1.3. The Guide on the decision-making process regarding medical treatment in end-of-life situations

The Guide on the decision-making process regarding medical treatment in end-of-life situations (hereafter, the *Guide*) published by the Committee on Bioethics of the Council of Europe on May 2014 has been analyzed by taking into consideration the Convention of Oviedo, and the Recommendations Rec(2003)24 and Rec(2009)11. In addition, some examples from national

legislations from the English-, German- and Romance-speaking countries will be given to illustrate and support these guidelines.

The *Guide* is composed of four chapters. Its goal is the implementation of the principles established in the Convention of Oviedo (e.g., see Sect. 1.1.), further enhanced by the Recommendation CM/Rec (2009) 11 (e.g., see Sect. 1.1.2.). While the Convention of Oviedo focuses on the concept of "previous expressed wishes" and the Recommendation (2009) 11 identifies special rules regarding the power of attorney, the *Guide* takes into consideration both them and also the role of the patient's family and relatives.

It should be noted that this guide does not take an official position regarding end-of-life issues. This would have been challenging since within the Council of Europe there is no ethical consensus, especially with its enlargement with the East European countries (Fan 1997). The main goal of this guide is to help the medical staff with the reflection on ethical principles regarding end-of-life decisions.

Furthermore, end-of-life is a difficult topic that involves not only physicians and patients, but also patients' families[94]. This has led to the conceptualization of the *transitional palliative care* approach, where patients, their families and health care team confront together the conceptualized

[94] The support to the family has been recognized as a guiding principle also in the Recommendation Rec (2003)24 of the Committee of Ministers of the Council of Europe

threat of possible imminent death (Nebel 2011, Thomas 2002, Harding 2003, Goldberg 2010). Therefore, the *Guide* could be also used – as a source of information – by patients and their families or relatives.

The transformation of the conceptualization of the palliative care is in harmony with the new concept of autonomy. According to the individualistic and liberal approach to autonomy physicians should give only cognitive information without interfering with the individual's decision-making process. This decreases the patient's trust in the physician role (Owens 2015, and Entwistle 2010) With the interpretation of autonomy as a relational principle, family dynamism (structure and relationships) (Broom and Kirby 2013) and interpersonal relationships (Rini et al. 2011, Corrigan 2004, and Lewis and Rook 1999) are considered important as well (e.g., see Sect. 1.2.). This is why the Recommendation CM/Rec (2009) 11 (e.g., see Sect. 2.1.2.) and the *Guide* highlight the importance of the social network of the patient.

In end-of-life decisions, three concepts are involved, which are decision, autonomy and end-of-life. The word "decision" comes from the Latin *de* and *caedere*, which etymologically means deciding, cutting off, or cleaving. Instead, the Greek word *auto-nomos*, where 'autonomy' comes from, means "living by one's own laws". Regarding the expression 'end-of-life', the Council of Europe has decided to take the French term established in the *Société Française d'Accompagnement et de Soins Palliatifs* (French Terminal and Palliative Care Society), which means that death is imminent and inevitable (Steering Committee on Bioethics 2008).

End-of-life decision is a difficult topic that involves different parties and the application of ethical, medical and legal principles. It includes: withholding or withdrawing potentially life-prolonging treatment (such as mechanical ventilation, tube-feeding, and dialysis), alleviation of pain or other symptoms that could have as a side effect hastening death (such as administration of opioids, benzodiazepines, or barbiturates) and even physician-assisted suicide (PAS) or euthanasia (Steering Committee on Bioethics 2008).

In this guide, PAS or euthanasia have not been addressed. The *ratio* of it has been that only few countries – such as the Netherlands, Belgium, Luxemburg, Switzerland (and to some extent, Germany[95]) – have legally ruled these types of medical activities. However, some reasons to include these medical practices could be given. Firstly, the title of this guide regards end-of-life situations in general. Besides, the *Guide* has been based on the two reports presented during the symposium of 2010,[96] and these reports – especially the one presented by Professor Lucie Hacpille – have included PAS and

[95] Before November 2015, in Germany, PAS was not legally prohibited by the national law. Nevertheless, Chamber of Physicians of some Lands – such as: Mecklenburg-Western Pomerania, Saxony, Lower Saxony, Thuringia, and Hesse – have prohibited it through disciplinary sanctions in the Medical Ethics Codes. However, it should be noted that recently the German Parliament has modified article 217 of the Criminal Code. The *Entwurf eines Gesetzes zur Strafbarkeit der geschäftsmäßigen Förderung der Selbsttötung* of 6 November 2015 passed through the positive votes of 360 members. This bill was introduced for the first time on 13 November 2014 and was discussed for the first time on 2 July 2015. The bill allows assisted suicide if the individuals who offer to help someone with suicide do not do that "on business terms" (*geschäftsmäßig*); otherwise they will face up to three years in prison or a fine. The main critique of this regulation regards the ambiguous language used. Several politicians have been discussed the meaning of *geschäftsmäßig.* One of them, the former Justice Minister Brigitte Zypries, said that the new regulation "will open an era of great legal uncertainty".

[96] The Steering Committee on Bioethics on 30 November and 1 December 2010 had organized the symposium on the decision-making process regarding medical treatment in end-of-life situations. This symposium was based on two reports – one by Professor Lucie Hacpille on "Medical decisions in end-of- life situations and the ethical implications of the available options" and the other by Professor Roberto Andorno entitled "The previously expressed wishes relating to health care Common principles and differing rules in national legal systems".

euthanasia. Moreover, some ethicists have argued that there is no intrinsic moral difference exists between killing and letting die (Perrett 1996, James 1975, Boyle 1977, Kuhse 1998)[97]. Also, the wrongful killing could not be justified based on the difference between action and omission (The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research 1993, Bundesgerichtshof 25 June 2001). Furthermore, some European studies (e.g., see Sect. 1.1.2.) have demonstrated that PAS and euthanasia are common in medical decisions. In addition, these highly debated medical practices should have been included in the *Guide* since this guide is not a legally binding document for the member states.

When faced with end-of-life decisions, physicians are obliged to make decisions according to the state of science. This is quite a challenge because in the last decades the number of articles published has increased drastically[98]. In addition, medical treatments depend on the individual patient's reaction (Jasmeet 2008). Therefore, the communication between the medical team and the patient, or in case of his or her incapacity with the legal representative,

[97] On the contrary: Oddie 1997, Childress 1985, Maguire 1984, Beauchamp 1989.

[98] MEDLINE, maintained by the National Library of Medicine (NLM), is the largest and most widely used index of the medical literature. (Lacroix and Mehnert 2002). A total of 8.1 million journal articles were published in MEDLINE between 1978 and 2001. Between 1978 to 1985 and 1994 to 2001, the annual number of MEDLINE articles increased 46%, from an average of 272,344 to 442,756 per year, and the total number of pages increased from 1.88 million pages per year during 1978 to 1985 to 2.79 million pages per year between 1994 and 2001. (Druss and Marcus, 2005).

the surrogate and/or his or her family should be considered fundamental (Thom and Campbell 1997, Thom et al. 2011).

During this process, these parties should take into consideration the well-known set of ethical principles as suggested by US-American ethicists Beauchamp and Childress (1979). These four ethical principles are explained in chapter II of this guide. The respect of patient autonomy means the respects for his or her advance directives (Lawrence and Brauner 2009).

Moreover, autonomy does not imply the right for the patient to receive every treatment he or she may request (R (Burke) [2005] EWCA Civ 1003), even in cases where a constitutional right to health exists, such as in Italy (e.g., see Sect. 1.1.). This has been established in par. 50 of the Recommendation Rec(2003)24.

The principles of beneficence and non-maleficence, established in articles 2 and 4 of the Convention of Oviedo, refer to the doctor's dual obligation to seek to maximize the potential benefit and to limit as much as possible any harm that might arise from a medical intervention (p.10). It follows that physicians should deliver only appropriate treatments and should withdraw disproportionate treatments (Keown 1997, Whiting 1995-1996). Therefore, when physicians decide to deliver a medical treatment they should take into consideration the relationship between risk-benefits and patient's expectation. Although there could be objective medical criteria that suggest that this treatment is proportionate, physician should consider the whole patient's situation. This is why recently the ethical and legal debate has been focused on the patient-physician's trust (Thom et al. 2011, Thom and Campbell 1997).

While treatment could be withdrawn – in case of disproportionate treatments – patient-care should never stop. The *Guide* distinguishes between the concepts of 'care' and of 'treatment'. Treatment aims to cure the patient's illness or to act on its causes to reduce the impact on the patient's wellbeing. Care includes them, and also other type of actions, which do not need medical skills (for instance, personal hygiene and comfort). When related to end-of-

life, treatment and care are intended to improve the patient's quality of life. Within the bioethical community there is no unique definition of quality of life (e.g., see Sect. 1.1.).

The fourth principle of medical ethics – justice – has been recognized in article 3 of the Convention of Oviedo. In health care system, justice means equitable access to health care. Therefore, this principle implies that available resources should be distributed as fairly as possible[99]. Since longevity has increased (European Commission 2012) and European countries have cut their public budgets (Leider 2012), informal care at home has become an important source of containing the public expenditure in the health care system[100]. This is why the Rec(2003)24 recognizes the significance of the informal care and considers the public intervention in palliative care through care facilities only in case when caregivers in the home become overburdened[101].

[99] Principle 8 *European Charter of Medical Ethics*

[100] The informal care reduces with 25% the potential demand for health care services. (Brugiavini and Jappelli, 2010)

[101] Setting and Services, Recommendation Rec(2003)24 of the Committee of Ministers of the Council of Europe, p.11-12

1.3.1. Guidelines regarding the main parties in the decision-making process

The *Guide* has been dedicated to the decision-making process by distinguishing two main parties. On one hand, the role of patients, their surrogates or legal representatives has been crystallized; on the other, physicians, care teams and clinical ethics committee.

The *Guide* has adopted a patient-centered approach. In case of a competent patient, he or she must make the decision him- or herself. Obviously, the patients have the opportunity to consult not only their physicians in charge, but also others. Nevertheless, the competent patient shall make the final decision. In case of children or incapable adults that are conscious (e.g. see Sect. 2.1.2.), their involvement in the decision-making process according to their level of comprehension is required (p. 16-17). This policy reflects not only the protection of the right to self-determination, but also a deontological principle. In case of an unconscious patient, medical decisions at end-of-life must be made according to the so-called *three-step hierarchy*. However, nowadays, this *hierarchy* is not always so clear (e.g., see Sect. 1.4). In addition, empirical studies have shown that for both staff and families, consideration of a patient's best interests generally took priority over the patient's wishes (Karasz 2010). Therefore, a combination between the patient's previous medical directives and the opinion of a legal proxy has a stronger effect (Escher 2014).

In addition, by taking into consideration principle 1, section 2 of the Rec (2009)11, in case that the decision should be made by a legal proxy, the attorney nominated by the conscious citizen should be preferred compared to the legal proxy nominated by the judge (e.g., see Sect. 2.1.2.). This policy avoids judicial and administrative proceedings, is faster and it further promotes the ethical principle of autonomy (Explanatory Report Recommendation CM/Rec (2009) 11, par. 49). This *ratio* has been adopted directly by some national parliaments; however, the Scottish Legislator or the

new French law of March 2015 seem to not follow this principle (e.g., see Sect. 2.1.2.).

This guide leaves all requirements for advance directives to the national legislation. Currently, all the national parliaments in the English, German and Romance-speaking countries – except Italy, Ireland and Northern Ireland – have legally-backed advance directives. Moreover, since the advance directives in written form have failed their expectation (Jox et al. 2008, Michalowski 2005, Fagerlin and Schneider 2004, Prendergast 2001, and Teno et al. 1997), with the aim to reconstruct patient's wishes, this guide has recognized the importance of the legal proxy and family or close relatives.

As it has been mentioned above, the *Guide* considers the role of physicians, care teams and clinical ethics committees. In addition, this guide stimulates the implementation of an ex-post review of end-of-life decisions. The objective of it is not to control the work of the physician, but should aim to enhance their own understanding of such situations in the future.

Some of the members of the care team include nurses, care assistants, psychologists, and members of paramedical professions, such as physiotherapists. They are in constant contact with the patient. Therefore, they have a closer relationship with the patient than the physician and (generally) recognize signs of medical futility sooner than doctors (Zerwekh 2005).

The exchange of information between doctors, especially in difficult medical decisions, has been one of the leitmotifs of Chapter III of this guide. This policy has been adopted by the French legislator in 2005 and again repeated with the new law of March 2015[102].

The focus of this guide is to help the care team to combine medical information with ethical principles. With the aim to help them in this process, clinical ethics committees are constituted. Within the English-, German- and Romance-speaking countries, the Italian legislator has codified their importance in the proposal 5 of 15 March 2013 and proposal 1142 of 4 June 2013[103].

It should be noted that this guide highlights the ethical and legal discussion regarding ANH and sedation in terminal phase. Although in none of

[102] The law of 2005 has recognized in cases established in article 1111-4, section 5 and article 1111-13, section 1 CSP an *ad hoc* collegial proceeding (R. 4127-37 CSP). The new law of 2015 has added another case in article 1111-5-1, section 1 CSP.

[103] In concrete, in case of unconscious patient where either advance directive no patient's legal proxy or family or relatives exits, the decision should be made by the internal clinical ethics committee [proposals 5 (article 4, section 4) and proposal 1142 (article 5, section 4)]. Moreover, in case that there is a contract between people that should give the consent on behalf of the unconscious patient, the decision should be made by the internal clinical ethics committee [proposals 5 (article 8, section 1) and proposal 1142 (article 9, section 1)]. Furthermore, physicians have the possibility to not execute a patient's living wills in case that the ethical committee of the hospital expresses its opinion that patient's current medical situation do not correspond with the situation the patient took into account at the time of issuing the living will due to the new medical discovery [proposals 5 (article 10, section 5) and proposal 1142 (article 11, section 5)].

these issues the *Guide* takes any official position, regarding artificial nutrition and hydration – without distinguishing between nasograstrofic *or* adminalgastrofic – it states that this technique implies choices concerning medical procedures and devices (perfusion, feeding tubes) (e.g., see Sect. 5.1.1. and 3.1.1.). The same conclusion has been reached by the British Medical Association (2007). From this premise, it derives that these kinds of care cannot be classified as basic care. Regarding sedation in terminal phase, the *Guide* highlights that the purpose of sedation is not to shorten life. In addition, the ethical debate regarding the use of this treatment for alleviating psychological or existential suffering has been reflected.

Before concluding it should be mentioned that this *Guide* does not mention the particular cases of persistent or permanent vegetative state; either it gives a definition regarding the concept of futile treatment (e.g., see Sect. 1.5.1. and 3.1.1.).

Concluding, it should be said that the main value of the *Guide on the decision-making process regarding medical treatment in end-of-life situations* consists in the explanation of the four ethical principles in the end-of-life issues. This document does not take any official position regarding debated bioethical topics, such as sedation or artificial nutrition and hydration. However, its usefulness consists in underlying that ANH cannot be qualified as basic care because it states that this technique implies choices concerning medical procedures and devices. In addition, the *Guide* makes a distinction between medical treatment and patient care in general and it brings again the attention to the application of the patient-centered approach. A review of previous decisions could help the process of end-of-life situations. Generally, national laws in the German-, English- and Romance-speaking countries are in harmony with these guidelines.

2. Advance directives in English, German, and Romance-speaking countries: similarities and differences

In all the countries studied, health is considered a constitutional right.[104] The extent of its protection varies from country to country:[105] its varies from a 'negative obligation' of the state to not to endanger citizens' health – as in Ireland – to the highest extent of protection of a 'right to health' –as in Italy. In all these countries, citizens have the right to refuse medical treatments.[106] All the countries studied except Italy, Ireland and Northern Ireland have legally-backed ADs (e.g., see Sect. 1.1.3.).

[104] It should be noted that United Kingdom of Great Britain and Northern Ireland has an 'unwritten constitution'. Nevertheless, health is considered so important that in England, on March 2012 the Department of Health published the National Health Service Constitution for England; a document that aims to regulate health care throughout England.

[105] Health is safeguarded as the 'right not to have one's health endangered by the State' in Ireland (preamble of the Constitution and Government of Ireland); as a 'legislative power' given to the federal state in Austria (article 10) and in Germany (article 74); as a result of enjoyment of the environment in France (article 1 of the Chapter for the environment); as a right or access to health care in Switzerland (article 41); as a 'protection of health' in Portugal (article 64) and Spain (article 43); and as a 'right to health' in Italy (article 32).

[106] Only in Italy, citizens have the right to demand for medical treatment; in all the other countries, medical treatment can be denied – despite patients' requests – not only because these medical treatments are considered as futile, but also for other legally defined reasons, for instance as a consequence of allocation of scarce resources. Physicians have the right to withdraw medical treatment in case that these are patently futile and excessively burdensome to the patient (Par. 50, Explanatory memorandum of the Recommendation Rec(2003)24 of the Committee of Ministers of the Council of Europe).

Although these countries share a basic consensus regarding the broad concept of the protection of patient autonomy,[107] different policies emphasize different values. In English and German-speaking countries, patient autonomy has been considered fundamental; its protection has been achieved through supporting people who lack capacity (in English-speaking countries)[108] or through underlining the importance of the patient's right to self-determination (in German-speaking countries).[109] In Romance-speaking countries, although patient autonomy is been recognized, a physician-centred

[107] Several scholars, including A. E. Buchanan, D. W. Brock, N. Rhoden, and R. Dworkin, have highlighted the importance of advance directives in end-of-life decisions. According to two of them, "advance directives are not merely evidence of what will be good for the later incompetent patient (which may be rejected when better evidence comes along), but are acts of self-determination"

(Buchanan and Brock 1990).

[108] In England: Joint Committee on the Draft Mental Incapacity Bill, "Draft Mental Incapacity Bill (1st Report, Session 2002-03, HL 189-I)" http://www.publications.parliament.uk/pa/jt/jtdmi.htm; in Ireland: Minister of State at the Department of Health (Deputy Kathleen Lynch) "Assisted Decision-Making (Capacity) Bill 2013: Second Stage" http://oireachtasdebates.oireachtas.ie/debates%20authoring/debateswebpack.nsf/takes/dail2013120300037?opendocument#KK00700; and in Scotland: Scottish Law Commission, "Report on Incapable Adults (Part 1)', (Scot Law Com No 151)" http://www.scotlawcom.gov.uk/publications/reports/1990-1999/.

[109]In Austria: Judiciary Committee. "Report of the law 2006 - SWRÄG 2006", http://www.parlament.gv.at/PAKT/VHG/XXII/I/I_01511/fname_063771.pdf; in Germany: Legal Commetee. "Reccomentation of the legal Commetee", http://dipbt.bundestag.de/dip21/btd/16/133/1613314.pdf ; and in Switzerland: Swiss National Advisory Commission on Biomedical Ethics. "Opinion 17/2011", http://www.nek-cne.ch/fileadmin/nek-cne-dateien/Themen/Stellungnahmen/en/NEK-CNE_Advance_Directives.pdf.

approach[110] and disadvantages of the implementation of ADs[111] have also been emphasized. Of these last, the Italian parliament has adopted the most paternalistic approach.[112]

Legislators are aware that laws cannot foresee every detail of end-of-life decisions. Therefore, some countries have empowered public bodies to discipline and manage national registers of ADs,[113] or just of surrogates;[114]

[110] In France: articles 1111-4 and 1111-13; in Italy (bill 2350): article 7 bill 2350; in Portugal: articles 5 and 9; in Spain: article 11, section 3.

[111] In France: National Assembly, 2008, 'Mission d'évaluation de la loi n° 2005-370 du 22 avril 2005 relative aux droits des malades et à la fin de vie n° 1287'. Retrieved 18 march 2015, http://www.assemblee-nationale.fr/13/dossiers/mission_fin_vie.asp; in Italy: National Commette of Bioethics, 2003, 'Dichiarazioni anticipate di trattamento'. Retrieved 18 march 2015, http://www.governo.it/bioetica/testi/Dichiarazioni_anticipate_trattamento.pdf In the Iberian countries risks arising from the implementation of ADs are highlighted through a strict bureaucratic model. In particular, in Spain most Autonomous Communities' regulations establish several formal requirements (Navarro-Michel 2005). The same strict bureaucratic model is used in the Portuguese law of 2012 (Pereira 2013).

[112] Bill 2350 was drafted under the Catholic Bioethics group: phrases such as 'protection of life', 'extraordinary treatment' – a term rejected by secular bioethicists – 'prohibition of any kind of euthanasia' – a term which never appears in the Italian Penal Code – appear as major principles in article 1 of this bill. However, the new draft-bills – except draft-bill 2226 – have adopted a liberal approach (e.g., see Sect. 1.1.3. and Chap. 3).

[113] In Italy (article 8, section 1), in Portugal (article 15, section 1), and in Spain (article 11, section 5) national Ministries of Health are responsible for running the national register of ADs. In France, the new law of March 2015 gives to the Council of State the duty to decide about the conservation of these documents (1111-11, section 4 CSP)

other have nominated a public body responsible for the implementation of these general norms;[115] and some legislators have established a national code of practice[116] or code of medical ethics[117] as an instrument to implement national law. Furthermore, in all these countries, national physicians' councils[118] govern the patient–physician relationship: in case of infringement

[114] In England (article 58, section 1), in Ireland (article 48, section 1), and in Scotland (article 6, section 1) the Public Guardian is responsible for establishing and maintaining a national register of surrogates.

[115] In Austria, the Federal Minister of Justice is responsible for the implementation of the *Sachwalterrechts-Änderungsgesetz 2006 – SWRÄG 2006,* law 23 June 2006, governing the role of surrogate, and the Federal Minister of Health and Women in agreement with the Federal Minister of Justice is responsible for the implementation of the *Patientenverfügungs-Gesetz – PatVG,* law of 8 May 2006, governing 'living wills'.

[116] In English-speaking countries the 'Code of practice' is to be established: in England, by the Lord Chancellor (article 42 of the Mental Capacity Act of 2005); in Ireland, the current version of the Bill emphasizes the importance of the role of the Public Guardian (article 63 of the Assisted Decision-Making (Capacity) Bill 2013); and in Scotland by the Scottish Ministers (article 13 of the Adult with Incapacity (Scotland) Act of 2000).

[117] In France, rules established in the Code of Medical Ethics can be considered an integral part of the French Public Health Code. These rules would become legally binding only if upheld by a judicial review by the French Council of State (according to the preamble of the Code of Medical Ethics).

[118] The exact names of the national councils of physicians are: in Austria, the Chamber of Physicians; in France, the National Medical Council; in Germany, the Chamber of Physicians; in Ireland, the Medical Council; in Italy, the National Federation of Associations of Physicians and Dentists; in Portugal, the Medical Association; in Spain, the General Council of Medical Colleges; in Switzerland, the Medical Association; and in UK, the General Medical Council.

of these rules, disciplinary sanctions are established directly[119] or indirectly[120] by them.

All national parliaments in English-, German- and Romance-speaking countries have recognized the right of patients to self-determination. ADs are not limited in time; however, some exceptions to this rule have been found. Austria (article 7, section 1, law of 8 May 2006), Portugal (article 7, section 1 law of 16 July 2012), and the Italian Bill (article 4, section 3 Bill 2350 and article 4, section 3 draft-bill 2229) limit the period of validity of ADs[121]. All these countries have implemented a time limit of 5 years. It seems that these legislators have adopted the philosophy of Derek Parfit (1984), who believes personal identity is not merely a question of physical continuity over time

[119] The disciplinary sanction in case of infringement of these rules is established directly: in Austria by article 12, section 3 Code of Conduct of 2014; in France by article 110 of the Code of Medical Ethics; in Italy by article 2 Code of Medical Ethics of 2014; in Portugal by article 155 Code of Medical Ethics of 2008; in Spain by article 2 Code of Medical Ethics of 2011; and in Switzerland by articles 43–49 Code of Medical Ethics of 2014.

[120] Disciplinary sanctions for infringement of these rules could derive from the interpretation of: in Germany, the preamble of the Code of Conduct of 2011; in Ireland, the combination of article 2, section 2 and article 3 of the Guide to Professional Conduct and Ethics for Registered Medical practitioners; and in UK, articles 72-76 of the Good Medical Practice.

[121] The old version of the French law established that advance directives have a validity of 3 years. Nevertheless, they could be renewed by a simple signature of the existing document (Article 1111-18 *Code de la Santé Publique*). On the contrary, the new version of the French Law of 2015 does not establish any time-limited of these documents.

(e.g., see Sect. 1.3.1.). Moreover, these policies base their rationale on the results of some empirical research that show patients' decisions change over time (Lingler et al. 2010, Witting et al. 2008, Ditto et al. 2003).

Moreover, rules for ADs have generally been established in distinct legal texts. France and German-speaking countries are exceptions to that rule. France is the only country in this study that has modified its *Code de la Santé Publique* (CSP, Public Health Code). Austria,[122] Germany, and Switzerland have modified their civil codes. It is notable that the political decision to include end-of-life decisions in either public code or civil code is in itself an important moral choice: public codes regulate citizens' activities in connection with the organs of the state, and civil law rules citizens' dealings with each other. The decision to include the regulation of ADs in public law expresses some kind of external control of citizens' health care decisions. On the other hand, the modification of the civil code – for instance in German-speaking countries – demonstrates that end-of-life decisions are considered a private matter for the individual sphere.

In all the countries surveyed, the significance of the role of a surrogate in health care decisions has been established. This recognition is important because some previous rules did not allow the power of attorney of personal welfare and established the forfeiture of the right to represent the person who

[122] The Austrian parliament has modified its civil code only with respect to the nomination of a surrogate.

had given the power once the mandator had become incapable or incompetent (e.g., see Sect. 2.1.2.).

Sometimes, the law on ADs mostly concerns the surrogate,[123] or highlights the role of surrogate.[124] In some cases, national laws specify who can be nominated as a surrogate;[125] in others, parliaments have established who cannot be a surrogate.[126] In general, every competent physical person can be nominated as surrogate. Further, in Switzerland, a legal person can also be nominated as a surrogate (article 360 ZGB), which is the only such case in the countries studied.

[123] In Germany, the law is directed to the guardian ('der Betreuer'). Nevertheless, these rules are applied to the surrogate ('der Bevollmächtigte') (article 1901a, section 3; article 1901b, section 3; article 1904, section 5 of BGB). In Scotland, the law rules the activity of the legal proxies (guardian and continuing or welfare power of attorney); same with the new bill of 2013 in Ireland (decision-making assistant, co-decision-maker, decision-making representative, informal decision-maker, and enduring power of attorney).

[124] According to article 25, section 2, let. b) MCA of 2005 the previous AD is not valid if, after the donor has conferred lasting power of attorney the authority to give or refuse consent to the treatment to which the advance decision relates. The same legal reasoning has been established in Ireland (article 6, section 2, let. b) of the Advance Healthcare Decision Bill 2012).

[125] For example, in France: article 1111-6 CSP states that a surrogate could be the parent, a relative or the attending physician.

[126] For example, in England article 10, section 1 states that the surrogate must be more than 18 years old; further, section 7.10 of the Code of Practice of the Mental Capacity Act states that people working as a paid care workers (such as a care home manager) – with only few exceptions – shall not be appointed as an attorney; and in Portugal, article 11, section 2 states that surrogates must be fully competent, therefore, not a minor, interdict or incapacitated person.

In the absence of a surrogate, some national parliaments have established a fixed order of precedence, which highlights the importance of the patient's family;[127] others have empowered an independent public body to nominate a surrogate in specific cases established by law.[128] The first approach could be effective in Mediterranean areas where empirical studies have shown that patients' family are typically given more information than patients themselves (Costantini et al. 2006, Robin et al. 2003), and where the majority of informal caregivers are relatives of the patient (Costantini et al. 2008, Rossi et al. 2007, Toro et al. 2007). The second approach is more effective in societies where a high rate of divorce exists.[129]

[127] In France, article 1111-13 CSP (the order is: surrogate, family, living wills); in Italy, article 6, section 8 bill 2350, which refers to book II, title II, chapter I and II (it is quite complicated; but (in general) the order is: children and spouse, siblings, parents); in Switzerland, article 378 ZGB (the order is: surrogate, person nominated in 'der Vorsorgeauftrag', guardian, spouse or registered partner, person living in the same household who regularly assists the incapable person, children if they regularly assist the incapable person, parents if they regularly assist the incapable person, brothers and sisters if they regularly assist the incapable person); in Spain: article 9, section 3 law of November 2002 states that if the patient is incapable and has no legal representative – even a surrogate – informed consent will be granted by virtue of relationship or de facto.

[128] In England, after nomination by the Independent Mental Capacity Advocate, the surrogate must ascertain the donor's wishes (article 36, section 2 let. c Mental Capacity Act); in Scotland, the Mental Welfare Commission can provide a welfare attorney when requested to do so (article 9, section 1, let. g of the of the Adult with Incapacity (Scottish) Act).

[129] Eurostat. "Crude marriage rate, selected years, 1960–2012" demonstrates that in 2011 the rate of divorce in UK is 2.1 and in Italy is 0.9.

In case of conflicts regarding the execution of ADs, a judge's ruling will be sought. However, in Italy, in Portugal, in Scotland, and in Switzerland, in certain cases decisions are taken by another public body.[130]

In no state policy studied has patient autonomy been denied. However, in Romance-speaking countries, while the patient's right to self-determination has been considered important, the physician's duty of care and the ethical principles of beneficence and non-maleficence have been also taken into account.

3. Advance Directives in Romance-speaking counties

http://ec.europa.eu/eurostat/statistics-explained/index.php/Marriage_and_divorce_statistics.

[130] In Italy, the first version of bill 2350 established an internal medical committee to resolve the conflict between surrogate and physician with a decision that would have had no legal binding force for physicians (article 7, section 3 bill 2350). In Portugal, only in case of medical conscientious objection, the hospital must find the best solution with other hospitals or physicians (article 9 law no. 25 of 16 July 2012). The Portuguese Law of AD is the only law in our study that explicitly establish medical conscientious objection in law. In Scotland, in case of conflicts between surrogate and physician, the decision will be taken by the 'nominated medical practitioner' from the Mental Welfare Commission (article 50, section 4 Adults with Incapacity (Scotland) Act). In Switzerland, the Adult Protection Authority will be in charge in cases where: 1) ADs are not carried out; 2) the patient's interest is endangered or not well protected; 3) ADs do not express the patient's free will (Article 373, section 1 ZGB).

The legal situation in Romance-speaking countries, especially Spain and France, has been analyzed in detail. In both these countries patient autonomy has been considered an important factor; notwithstanding, physicians' role in end-of-life decisions and disadvantages arising from the implementation of ADs are highlighted.

Of the Romance-speaking countries, Spain was the first country to regulate ADs. Compared with the other countries studied, the Spanish rules are the most precise: in just one article, ADs are established in all their details regarding surrogates, form, effectiveness, and the national register.[131] It should be mentioned that, compared to the other Romance-speaking countries, the Spanish law takes the most liberal approach.

In France, law no. 348 of 17 March 2015 has confirmed the physician-centred approach of the law 2005-370 of 22 April 2005, which has been considered a reaction to the case-law of Vincent Humbert, a tetraplegic patient who publically claimed the right to euthanasia (Pereira 2007, Dupont 2005). France is the only country in our study that has modified its Public Health Code.

[131] However, the Parliaments of the Autonomous Communities can establish further detailed rules (Navarro-Michel 2005).

3.1. Advance Directives in Spain

In Spain, the *Básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica* of November 2002 governs ADs. The Spanish law was considered as a model for the Portuguese law of 2012.[132]

Article 11, section 3 limits the patient autonomy. This section exemplifies the physician-centred approach.[133] According to it, prior medical

[132] Article 5 of the Portuguese law no. 25 of 16 July 2012 is similar to article 11, section 3 of the Spanish law no. 41 of 14 November 2002. Article 5 states that ADs are not applied in case of: 1) instructions contrary to the law, public order or good medical practices (the Spanish law uses the term 'instructions that are contrary to the law, or to the lex artis'); 2) instructions that could provoke the commission of crimes established in articles 134 and 135 of the Criminal Code; 3) instructions in which the executor's will is not clearly and unequivocally expressed (the Spanish law describes instructions which fail to 'correspond to the situation the interested party was considering at the moment of stating them').

[133] The physician-centred approach of the law 41 is also expressed elsewhere. Article 5, section 3 (repeated in article 9, section 3, let. A) considers physicians' opinion essential. Physicians – without oversight from another impartial public organ or by an internal body within the hospital – can decide that patients lack the capacity of understanding. For a better understanding of this policy it should be remembered that the Spanish legislature of 2002 took as a model the law of Catalonia no. 21 of 29 December 2000. According to the Catalan law physicians can establish a patient's incompetency (article 7, section 2, let. A). This rule has two main problems. First of all, it should be noted that there is a difference between the legal concept of 'competency' and the clinical and ethical concept of 'capacity'. To be competent is to have sufficient mental capacity for a given task, and is a question of fact, not of law. (Steinbock 2009). Secondly, physicians can never establish the incompetence of a person, which needs a judicial proceeding.

instructions contrary to the law or to the 'lex artis'[134] – understood as 'good medical practices' – or that do not correspond with the situation the patient took into account at the time of issuing them, should not be applied.[135] While the meaning of 'instructions that are contrary to the legal code' is clear,[136] doubts have been raised in the other two cases.

In accordance with this law, article 36, section 4 of the Code of Medical Ethics states that doctors must apply a patient's ADs, except when these directives are contrary to good medical practice. Since the General Council of Medical Colleges is responsible for defining the meaning of 'good medical practices',[137] it seems that the Spanish legislator has given to this public body –

[134] It must be underlined that Andalucía is the only Autonomous Community that does not establish this kind of limitation: article 7 of the Andalucía law 5 of 9 October 2003, *Ley de declaración de voluntad vital anticipada,* states that the patient's instructions will prevail over any physician's, family member's or surrogate's opinion.

[135] It should be noted that the AD will remain valid in such a case, but that specific petition will not be applied. In all these cases, prior instructions do not have legally-binding force, but shall be taken into account.

[136] As in all the Romance-speaking countries, ADs can contain only negative obligation of *'non facere'* against physicians. So, no instructions for assistance in suicide or euthanasia (article 143 Spanish Penal Code) will be executed.

[137] In its 2009 publication 'Conceptos 'Atención Médica al Final de la Vida'' ('Concepts of 'Health Care at end-of-life''), the General Council of Medical Colleges of Spain defines 'good medical practices' as proportional therapeutic treatments that avoid abandonment, futile treatment, or directly shortening life (section 2.9). Moreover, in its document of May 2010, 'El Consentimiento informado en la práctica medica' ('Informed Consent in Medical Treatments'), 'good medical practices' has been considered as the obligation to identify in each treatment the scientific, the technical,

which represents physicians' interests – the right to decide which medical directives will be applied.

Although in other countries a patient's instructions against 'good medical practice' have no effect, the Spanish statute explicitly enshrines this principle in the national law. This policy does not take into consideration that historically physicians have been criticized for paternalism and for wishing to have control over their patients' health (Devettere 1995).

In addition, ADs that do not correspond to the situation the writer was considering at the time of stating are not applied. This limitation has raised several problems. It is quite impossible to predict all the possible diseases that entail incapacity and all medical treatments that could be used in these cases. Moreover, some ADs are vague and ambiguous (Holley 2005); others are too specific and are not applicable in the concrete medical situation (Fagerlin et al. 2002). Further, some prior medical instructions do not focus on medical conditions or illnesses, but on their effects (Olick 2014). In all these cases a strict interpretation of article 11, section 3 requires that the ADs not be executed. Since the law does not establish the person responsible for examining whether these prior wishes correspond to the current living and

the legal and the deontological aspects (p. 11). Therefore, in defining 'good medical treatment', the medical scientific and technical knowledge are considered essentials.

treatment situation,[138] and ADs are documents used to implement the patient–physician relationship (British Medical Association 1995), it follows that the final decision as to their execution lies with the physician in charge.

Article 11 of the Spanish law of November 2002 recognizes the importance of ADs. Nevertheless, the Spanish Parliament of 2002 has adopted a physician-centered approach: its section 3 explicitly establishes that instructions against 'good medical practice' shall not be applied, and this law does not establish a neutral medical person to interpret the patient's prior instructions.

3.2. Advance Directives in France

In France, the *Loi relative aux droits des malades et à la fin de vie* of April 2005, modified by the *Loi créant de nouveaux droits en faveur des malades et des personnes en fin de vie* of March 2015, governs ADs.

The ethical principles of beneficence and non-maleficence are emphasized in several parts of this law; this is why in the case of a competent patient, the patient must repeat the refusal of medical treatments within a

[138] In Germany, the law explicitly states that the legal proxy (guardian or surrogate) must examine whether these determinations correspond to the current living and treatment situation (article 1901a BGB).

reasonable time, also by asking another physician (article 1111-4, section 2 of CSP).[139]

The physician-centered approach of this law could be explained by the strong influence of Rousseau's philosophy of the social contract on French legal culture (Horn 2014). Rousseau stated that every individual's opinions and preferences are subject to the general will that represents the community's interests (Rousseau 1762). According to the report of the French Bioethical Committee, physicians are considered to be representatives of society and should be allowed to make rational decisions on behalf of sick citizens (French National Medical Council 2000). Thus, French doctors will make their decisions based on 'professional consensus' or 'medical criteria' and not based on the patient's wishes (Horn 2014).

Moreover, the French National Medical Council has the power to integrate the French Public Health Code through the Code of Medical Ethics.[140] Although these rules can be adopted only in disciplinary proceedings, the French Council of State – after a judicial review – could establish their legality. Even legislatures of the English-speaking countries allows other public organs to implement their national acts regarding end-of-life decisions; but in those countries, detailed rules come from bodies not biased towards physicians (e.g., see *supra* note 117).

[139] The French law does not define the meaning of 'all that is possible'.

[140] Preamble and article 110 of the new Code of Medical Ethics of November 2013.

In addition, this law has established an *ad hoc* collegial proceeding in two cases (R. 4127-37 CSP). The first case is the case of limitation or withdrawal of treatments where there is a risk of death (article 1111-4, section 5 CSP); the second is the limitation or withdrawal of disproportionate treatments, or treatments which aim is to prolong life artificially (article 1111-13, section 1 CSP)[141]. In these cases, no decision to limit or withdraw treatment can be taken before other doctors have been consulted. Moreover, the decision is taken by the doctor treating the patient after consultation with the healthcare team.[142] In these cases the physician should also consult the patient's directives, or in absence of them, the patient's surrogate or family (article 1111-4 CSP).[143]

France, like Spain, has adopted a physician-centered approach. However, the French parliament has adopted a more conservative approach

[141] This policy has been confirmed by the new French law of 2015, which abrogated article 1111-13 and added article 1111-5-1 CSP that states that the collegium proceeding must be applied in case the treatment has no effect other than the artificial promulgation of life.

[142] Article 37 Code of Medical Ethics.

[143] The previous version of article 1111-4 CSP, into force from April 2005 until March 2015, stated that the patient's directives are considered only when there is neither a surrogate nor family members to consult. This policy follows French cultural norms, where (generally) families do not defer to the patient's directives, and many physicians do not consider a patient's living wills as a significant factor in their decisions. An empirical study conducted in December 2009 showed that ADs were written by only 1.5% of patients, and only 72% of physicians considered them to be significant in reaching their decisions (Pennec et al. 2012).

since an *ad hoc* collegial proceeding has been established in two cases. Additionally, doctors must do all that is possible to convince competent patients not to refuse medical treatments.

4. Advance Directives in English-speaking countries

The legal situation in English-speaking countries, in particular in England, where the patient's right to self-determination has been considered the major principle underlying ADs, has been analysed.

In England, the Mental Capacity Act of April 2005 governs ADs, and reflects the English liberal tradition – which goes back to the work of Locke (1690) and Mill (1865) – and protestant influence (Dickenson 1999). Moreover, in England, the patient's right to self-determination has been considered fundamental by both the bioethical community (General Medical Council 2008) and the judiciary (e.g., see Sect. 1.5.). All laws of the United Kingdom apply similar principles in end-of-life decision-making;[144] principles

[144] Regarding the citizen's capacity, the role of the Public Guardian, the importance of the Code of Practice, and the role of the independent organ to assist with information or advices legal proxies see Sect. 2.1.2. and 2.2. Moreover, acts in both Scotland and England confer on the relevant judicial body a similar power of control over legal proxies (in England, the Court of protection, articles 22–33 of the Mental Capacity Act; in Scotland: the power of the sheriff, article 3 of the Adult with Incapacity (Scotland) Act). Furthermore, in both these countries, a third party (in Scotland, a solicitor) certifies that the person who gives the power of attorney and the person

that have been used as a model for the Assisted Decision-Making (Capacity) Bill 2013 in Ireland.[145]

4.1. Advance Directives in England

In England, the MCA of April 2005 governs ADs. The liberal approach of this act is reflected in the procedural norms regarding 'living wills', in the codification of the 'new' definition of the term 'patient's best interest', in the creation of the lasting power of attorney (LPA), and in the creation of the Court of Protection.

who accept this power have understood their roles and duties (in England, the donor–donee relationship must be certified as per article 7.7 of the Code of practice of the Mental Capacity Act; in Scotland, the solicitor certifies the relationship between granter–welfare attorney according to article 15 of the Adult with Incapacity (Scotland) Act).

[145] Regarding the citizen's capacity, the role of Public Guardian, the importance of the Code of Practice, and the role of the independent organ to assist with information or advices legal proxies see Sect. 2.1.2. and 2.2. In addition, in Ireland, as in England, the relationship between the person who gives the power of attorney and the person who accept this power is defined as a donor–attorney relationship, where the attorney is called the 'donee of an enduring power' (article 38). Furthermore, the role of the judicial body (which is exercised through Circuit Courts and in some specific cases by the High Court) and the role of the Public Guardian have been underlined. As in England, the Courts can decide directly or through an appointment of a decision-making representative (article 23 Assisted Decision-Making (Capacity) Bill 2013; in England this person is called 'deputy' as per article 16 of the Mental Capacity Act).

In England, the refusal of medical treatments through living wills must be in written form.[146] In addition, when refusing life-prolonging treatment this document must be signed by the writer – or by another person at the writer's direction – in presence of a witness who must also sign it, or at least acknowledge the donor's signature (article 25). Further, when withdrawing ANH from a patient in a persistent vegetative state (PVG) – a patient who is in a vegetative state for longer than 6 months – or in a condition similar to PVG, a declaration by the court should be sought (e.g., see Sect. 1.5). However, ADs refusing basic care[147] is not legally binding.

Contrary to the continental definition of the term 'patient's best interest', where the term refers mainly to objective medical criteria such as diagnosis, prognosis, life expectancy, and the nature of pain (Pope 2011), in England, this term also refers to the patient's past and present wishes and feelings (article 4, section 6, letter a). This policy codifies the decisions of

[146] Section 5.45 of the Code of Practice of Mental Capacity Act. However, according to section 9.24 of the Mental Capacity Act Code of Practice in case of a person unable to write, a family member or the physician can record their oral statements. Further, in cases where the donor's signature is needed, another person can sign on the donor's behalf and in their presence.

[147] Basic care comprises all treatments designed to provide comfort to the patient or alleviate symptoms or distress. This includes warmth, shelter, hygiene (such as the management of incontinence), the offer of oral nutrition and hydration, and the provision of analgesia.

English courts since the turn of the millennium.[148] Therefore, the English principle of the patient's best interest is close to the principle of substituted judgement[149] in the continental Europe. Although this is not equal to the theory of substitutive judgment, medical treatment should be taken based on the 'patient point of view' (Aintree University Hospitals NHS Foundation Trust [2013] UKSC 67, §45, §24.).

The MCA introduced the LPA for the donor's welfare. The attorney must be registered with the Public Guardian. In England, citizens have the opportunity to choose more than one surrogate; and when they do so they can choose the procedural rules (article 10, section 4).[150] Therefore, England is the only country in this study to explicitly enshrine in national law the possibility established in principle 4, section 2 of the Recommendation CM/Rec (2009) 11 (e.g., see Sect. 2.2.2.).

In the cases where there is no LPA for the donor's welfare, but the donor has given an LPA for their property and affairs, this latter donee should be consulted about health care decisions (section 5.49 of the Code of Practice

[148] Re A [2000] 1 F.L.R. 193 and Simms v. Simms and another [2003] 1 All E.R. 669. These rulings included in the concept of 'best interest' emotional and other welfare issues. Beforehand, 'best interest' was limited to objective medical criteria F. v. West Berkshire Health Authority [1989] 2 All ER 545.

[149] The substituted judgement doctrine was rejected by the English courts in the case of Tony Bland in 1993 (e.g., see Sect. 1.5)

[150] The maximum number of LPAs is 5 (article 6 The Lasting Powers of Attorney, Enduring Powers of Attorney and Public Guardian Regulations).

of the Mental Capacity Act). Instead, for patients with no LPA or close relatives, an independent mental capacity advocate must be consulted (Article 25 Mental Capacity Act in accordance with section 5.49 and Chapter X of the Code of Practice of the Mental Capacity Act.)

When there is conflict between surrogate – or other people representing the patient – and physicians regarding the patient's best interest and medical treatment, the Court of Protection can decide directly or by appointing a person, called the *deputy*[151] (articles 45–53 MCA). In some cases the Court of Protection is absolutely required to intervene.[152]

In England, prior medical instructions are legally binding. Patients' wishes are prioritized by the 'new' interpretation of 'patient's best interest'. Moreover, health care decisions are considered a private matter, where the decision of the judge – through the 'new' Court of Protection – will be sought only if required or if there is a conflict regarding the patient's best interest and medical treatment.

[151] The political decision of the English parliament of 2005 is that the donee must be considered more important than the deputy because the LPA for welfare enhances patient autonomy. This is why the deputy can under no circumstances refuse consent to life sustaining treatment (article 20, section 5); but the donee can if explicitly authorized (articles 11 section 7 letter c and 11 section 8 letter a).

[152] The decision of the Court of Protection is required in case of serious medical decisions for incapable patients in: 1) withdrawing ANH for a patient in PVS; 2) proposed non-therapeutic sterilisation; and 3) other cases involving ethical dilemmas in untested areas, or where there are otherwise irresolvable conflicts between professionals, or between professionals and family members. (Shickle 2006)

5. Advance Directives in German-speaking countries

The legal situation in German-speaking countries, in particular in Germany, where the patient autonomy has been considered the major principle, has been examined.

In Germany, the law *Drittes Gesetz zur Änderung des Betreuungsrechts* of July 2009 regulates ADs, and is mainly devoted to the rights and duties of legal proxies. As in England, a patient's right to self-determination is considered essential by both the bioethical community (Neitzke et al. 2006) and the Federal Court.[153] Germany, as well as Austria (only regarding the nomination of a surrogate) and Switzerland, have introduced norms regarding ADs in their civil codes.

[153] The Federal Court recognized the importance of substitutive judgment (Bundesgerichtshof: 1994, BGHSt 40, 257 (263)=BGH 1 StR 357/94, 13 September 1994) and established the binding nature of advance directives (Bundesgerichtshof: 2003, BGHZ 154, 205 (217)=XII ZB 2/03, 17 March 2003) before the German Parliament ruled it on 2009.

5.1. Advance Directives in Germany

In Germany, the *Drittes Gesetz zur Änderung des Betreuungsrechts* of July 2009 regulates ADs. The liberal approach of this law becomes apparent in the absence of formal norms regarding the composition of ADs, in the binding force of previously verbally-expressed specific treatment preferences, and in giving the power to the Court of Guardianship in cases of disagreement between the attending physician and the legal proxy concerning the patient's wishes.

This law is considered rather liberal (Wiesing et al. 2010), which is probably the result of the fact that the issue of ADs was a bottom-up development, as a societal movement resulting in the demand for a political decision (Evans et al. 2012). While in 2002 only 2.5% of German citizens had an AD (Schroder et al. 2002), in 2007 – two years before the approval of the final law regarding ADs – this number increased to approximately 10% (Lang and Wagner 2007, Lang et al. 2007). As a consequence of this liberal approach to end-of-life decision-making, no national register for ADs in general – as in Spain, Portugal, or Italy – or for 'surrogate wills' in particular – as in English-speaking countries – has been established. Neither the role of physicians nor risks arising from the implementation of ADs – as in Romance-speaking countries – has been considered.[154]

[154] It should be mention that during the parliamentary discussion two opposing bills adopting a more conservative approach were discussed. These bills were proposed

The law presupposes the legally-binding nature of ADs (Wiesing et al. 2010). The wishes of a patient unable to consent must be sought on three different levels, in decreasing order of precedence: 1) living wills; 2) formerly expressed treatment wishes (*Behandlungswünsche*); and 3) presumed wishes. Only living wills are required as a written document; no legal obligation for notarization of medical information has been established. Also, oral declarations are legally valid (e.g., see Sect. 2.1.2.).

In cases of disagreement between a surrogate and a physician about a patient's wishes, the courts must be involved. According to article 1904 BGB, the Courts of Guardianship (*Betreuungsgericht*), are only responsible for cases of conflicts between guardian (or surrogate) and physicians in charge of the patient concerning patient preferences. This is a codification of the decision of the civil court of the Federal Court of Justice (e.g., see Sect. 1.5. and 2.5.) that, in 2003, stated that withholding or withdrawing treatment does not need a court's approval with the exception of cases in which physicians and patient's legal proxy disagree about the patient's will. The court then has to establish the patient's wishes.

In Germany, as in England, ADs are legally binding. Health care decisions have been considered to belong to the personal sphere and a judge's ruling will be sought only in cases of conflicts regarding the patients' wishes.

by Wolfgang Bosbach (Christian Democrat) and by Wolfgang Zöller (Christian Social Union).

Compared to the English legislature, the German parliament has adopted a more liberal approach: neither a national register for ‘surrogate wills’ has been created nor have formal requirements regarding ‘living wills’ been established.

Summary

The common European standard in end-of-life situations has been demonstrated through the analysis of the European Convention on Human Rights and Biomedicine, the Recommendation CM/Rec (2009) 11 and the *Guide on the decision-making process regarding medical treatment in end-of-life* of May 2014. In addition, the different approaches in the national policies of ADs between Romance-, English-, and German-speaking countries has been delineated by examined, particularly the policies in Spain, France, England and Germany.

The European Convention on Human Rights and Biomedicine is the first international legally binding comprehensive multilateral treaty addressing human rights issues in biomedicine. It can be seen as *lex specialis* of the European Convention on Human Rights of 1950 (Application no. 8278/1978). In addition, the Recommendation CM/Rec (2009) 11 shows the common European standard in end-of-life decisions. Therefore, the European Court on Human Rights might apply this recommendation, although it is considered a *soft-law.* Moreover, the main value of the *Guide on the decision-making process regarding medical treatment in end-of-life situations* consists in the explanation of the four ethical principles in the end-of-life issues. In addition, the *Guide* makes a distinction between medical treatment and patient care in general and it brings again the attention to the application of the patient-centered approach.

In the second part of Chap. 2, the detailed analysis of the policies of Spain, France, England and Germany has shown the different approach towards end-of-life decisions. Spain and France – although safeguard the patient's right to self-determination – have adopted a physician-centered approach. In Spain, since the law does not establish the person responsible for examining whether the prior wishes correspond to the current living and treatment situation and ADs are documents used to implement the patient–physician relationship, it follows that the final decision as to their execution lies with the physician in charge. Moreover, the French parliament has

adopted a more conservative approach since an *ad hoc* collegial proceeding has been established in two cases, cases that regard the withdrawal of treatments. It should be noted that the French legislator of 2015 has applied a more liberal approach compared to the law of 2005 because advance directives are presumed to be legally binding and not time-limited. However, the law no. 348 of 17 March 2015 has confirmed the physician-centred approach of the law 2005-370 of 22 April 2005

On the other hand, in England and in Germany, the role of physicians has not been underlined and patient autonomy has been the only value protected by the national legislators. In both these countries, health care decisions have been considered to belong to the personal sphere and a judge's ruling will be sought only in cases of conflicts regarding the patients' wishes. Compared to the English legislature, the German parliament has adopted a more liberal approach since in Germany it exists an absence of formalities regarding living wills or surrogate wills. In addition, with the scope to underline the liberal approach in end-of-life issues, on November 2015, the German parliament has modified article 217 of the Criminal Code by allowing assisted suicide if the individuals who offer to help someone with suicide do not do that "on business terms" (*geschäftsmäßig*).

Concluding, the Council of Europe and the European Court of Human Rights have established the basic common European background in end-of-life situations. Nevertheless, national policies differ from each other since different parliaments have protected different moral values. Within all the national policies analysed, the German parliament has adopted the most liberal approach.

References:

Andorno, Roberto. "An Important Step in the Promotion of Patients' Self-Determination" *European Journal of Health Law* 17, no. 2 (2010): 119-124.

Andorno, Roberto. "The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law." *Journal of International Biotechnology Law* 2, no. 4 (2005): 133-143

Andorno Roberto. "Biomedicine and international human rights law: in search of a global consensus." *Bulletin of the World Health Organization* 80, no. 12 (2002): 959–963.

Beauchamp, Tom L. "A Reply to Rachels on Active and Passive Euthanasia." In *Contemporary Issues in Bioethics*, edited by Beauchamp Tom L. and LeRoy Walters, 248-255. Belmont: Wadsworth Publishing Company, 1989.

Beauchamp, Tom L., and James F. Childress. *Principles of Biomedical Ethics*. New York: Oxford University Press, 1979.

Boyle, Joseph M. "On Killing and Letting Die." *The New Scholasticism* 51, no. 4 (1977): 433-452.

Braun Kathrin*. Menschenwürde und Biomedizin. Zum philosophischen Diskurs der Bioethik*. Frankfurt: Campus, 2000.

British Medical Association. *Advanced Statements about Medical Treatment.* London: BMJ Publishing Group, 1995.

Broom, Alex and Emma Kirby "The end of life and the family: hospice patients' views on dying as relational." *Sociology of Health and Illness* 35, no. 4 (2013): 499-513.

Brugiavini Agar and Tullio Jappelli, *Verso un nuovo sistema di architettura sociale per la famiglia: rischi economici e domanda di assicurazione*. Bologna: il Mulino, 2010.

Buchanan, Allen and Dan W. Brock. *Deciding for Others: The Ethics of Surrogate Decision Making*. Cambridge: Cambridge University Press, 1990.

Childress James F. "Love and Justice in Christian Biomedical Ethics." *Philosophy and Medicine* 20, (1985): 225-243.

Corrigan, Patrick. "How Stigma Interferes with Mental Health Care." *American Psychologist* 59, (2004): 614–625.

Costantini, Massimo and others. "Cancer trajectories at the end of life: is there an effect of age and gender?" *BMC Cancer* 2, no. 8 (2008): 127.

Costantini, Massimo and others. "Diagnosis and prognosis disclosure among cancer patients. Results from an Italian mortality follow-back survey." *Annals of Oncology: Official Journal of the European Society for Medical Oncology / ESMO* 17, no. 5 (2006): 853–859.

Devettere, Raymond J. *Practical decision making in health care ethics: cases and concepts*. Washington: Georgetown University Press, 2010.

Dickenson, Donna L. "Cross-cultural issues in European bioethics." *Bioethics* 13, no. 3-4 (1999): 249–255.

Ditto, Peter H. and others "Stability of older adults' preferences for life-sustaining medical treatment." *Health psychology : official journal of the Division of Health Psychology, American Psychological Association* 22, no. 6 (2003): 605–615.

Druss Benjamin G. and Steven C. Marcus. "Growth and decentralization of the medical literature: implications for evidence-based medicine." *Journal of the Medical Library Association : JMLA* 93, no. 4 (2005): 499-501.

Dupont, Bernard M. "Refuse a 'Vincent Humbert law'." *Médecine Palliative* 4, no. 6 (2005): 309-311.

Entwistle, Vikki and others. "Supporting Patient Autonomy: The Importance of Clinician-patient Relationships." *Journal of General Internal Medicine* 25 (2010): 741–745.

Escher, Monica and others. "Impact of advance directives and a health care proxy on doctors' decisions: a randomized trial." *Journal of Pain and Symptom Management* 47, no. 1 (2014): 1-11.

Evans, Natalie and others. "A critical review of advance directives in Germany: attitudes, use and healthcare professionals' compliance." *Patient Education and Counseling* 87, no.3 (2012): 277-288.

European Commission "Long-term care: need, use and expenditure in the EU-27." http://ec.europa.eu/economy_finance/publications/economic_paper/2012/pdf/ecp469_en.pdf

Explanatory Report of the Convention on Human Rights and Biomedicine No. 164/1996

Fagerlin, Angela and Schneider, Carl E. "Enough. The Failure of the Living Will." *The Hastings Center Report* 34, no. 2 (2004): 30–42.

Fagerlin, Angela and others. "The use of advance directives in end-of-life decision making." *American Behavioural Scientist* 46, no. 2 (2002) 268–283.

Fan, Ruiping. "Self-Determination vs. family-determination: two incommensurable principles of autonomy." *Bioethics* 11, no. 3-4 (1997): 309-322.

Faunce, Thomas A. "Will international human rights subsume medical ethics? Intersections in the UNESCO Universal Bioethics Declaration." *Joulnal of Medical Ethics* 31, no. 3 (2005): 173-178.

French National Medical Council. Avis sur Fin de vie, arrêt de vie, euthanasie. http://www.ccne-ethique.fr/sites/default/files/publications/avis063.pdf

General Medical Council. "Consent: Patients and doctors making decisions together" http://www.gmc-uk.org/static/documents/content/Consent_-_English_0914.pdf;

General Medical Council. "Treatment and care towards the end of life: Good practices in decision making" http://www.gmc-uk.org/End_of_life.pdf_32486688.pdf.

Goldberg, Jaime H. "Family Carers in Palliative Care: A Guide for Health and Social Care Professionals." *Journal of Palliative Medicine* 13, no. 3 (2010): 339–340.

Goffin, Tom and others. "Why eight EU Member States signed, but not yet ratified the Convention for Human Rights and Biomedicine." *Health Policy* 86, no. 2-3 (2008): 222-233.

Harding, Richard and Irene J. Higginson. "What is the best way to help caregivers in cancer and palliative care?." *Palliative Medicine* 17, no. 1 (2003): 63–74.

Holley, Jean L. "Palliative care in end-stage renal disease: focus on advance care planning, hospice referral, and bereavement." *Seminars in Dialysis* 18, no. 2 (2005): 154–156.

Horn, Ruth "'I don't need my patients' opinion to withdraw treatment'': patient preferences at the end-of-life and physician attitudes towards advance directives in England and France'." *Medicine, Health care, and Philosophy* 17, no. 3 (2014): 425-435.

Howard, Robinson. "Dualism." In *The Stanford Encyclopedia of Philosophy,* edited by Edward N. Zalta, 2003. http://plato.stanford.edu/entries/dualism/

James, Rachels. "Active and passive euthanasia." *The New England journal of medicine* 292, no. 2 (1975): 78-80.

Jasmeet, Soar and others. "Emergency treatment of anaphylactic reactions Guidelines for healthcare providers." *RESUSCITATION* 77, no. 2 (2008): 157-169.

Jox, Ralf J. and others. "Substitute decision making in medicine: comparative analysis of the ethico-legal discourse in England and Germany." *Medicine, Health care, and Philosophy* 11, no. 2 (2008): 153-163.

Karasz Alison, and others. "The rational choice model in family decision making at the end of life." *The Journal of Clinical Ethics.* 21, no. 3 (2010): 189-200.

Keown, John "Restoring Moral and Intellectual Shape to the Law after *Bland.*" *The Law Quarterly Review* 113, (1997): 481-503.

Knowles, Lori P. "The lingua franca of human rights and the rise of a global bioethics." *Cambridge Quarterly of Healthcare Ethics : CQ : the International Journal of Healthcare Ethics Committees* 10, no. 3 (2001): 253-63.

Kuhse Helga. "Why Killing is not Always Worse – and Sometimes Better – Than Letting Die." *Cambridge Quarterly of Healthcare Ethics* 7, no. 4 (1998): 371-374.

Lacroix Eve M. and Robert Mehnert. "The US National Library of Medicine in the 21st century: expanding collections, non traditional formats, new

audiences." *Health Information and Libraries Journal* 19, no. 3 (2002): 126–132.

Lang, Frieder R. and Gert G. Wagner. "Patient living wills in Germany: conditions for their increase and reasons for refusal." *Deutsche medizinische Wochenschrift* 132, no. 48 (2007):

2558–2562.

Lang, Frieder R. and others. Desired lifetime and end-of-life desires across adulthood from 20 to 90: a dual-source information model." *The Journals of Gerontology. Series B, Psychological Sciences and Social Sciences* 62, no. 5 (2007): 268–278.

Lawrence, Ryan E., and Daniel J. Brauner, "Deciding for others: limitations of advance directives, substituted judgment, and best interest." *Virtual Mentor VM* 11, no. 8 (2009): 571-581.

Lecaldano, Eugenio. *Bioetica. Le scelte morali.* Bari-Roma: Laterza, 2005.

Leider John P., and others. "Public health spending in 2008: on the challenge of integrating PHSSR data sets and the need for harmonization." *Journal of Public Health Management and Practice : JPHMP* 18, no. 4 (2012): 355-363.

Letsas, George. "Strasbourg's Interpretive Ethic: Lessons for the International Lawyer." *European Journal of International Law* 21, no. 3 (2010): (509-541)

Lewis, Megan A. and Karen S. Rook "Social Control in Personal Relationships: Impact on Health Behaviors and Psychological Distress." *Health Psychology* 18, no. 1 (1999): 63–71.

Lingler, Jennifer H. and others. "Temporal stability of receptiveness to clinical research on Alzheimer disease in Alzheimer disease." *Alzheimer Disease and Associated Disorders* 24 (2010): S30-4.

Locke, John. *The two treatises of government*. London: Everyman Paperback, 1993. [original work published 1690].

Maguire Daniel C. *Death by Choice.* Garden City: Doubleday & Company, Inc., 1984.

Michalowski, Sabine. "Advance Refusals of Life-sustaining Medical Treatment: the Relativity of an Absolute Right." *Modern Law Review* 68, no. 6 (2005): 958–982.

Mill, John S. *On liberty*. New York: Simon & Brown, 2012. [original work published 1865].

Navarro-Michel, Monica. "Advance Directives: the Spanish Perspective." *Medical Law Review* 13, no. 2 (2005): 137-169.

Nebel, Sara. "Facing death together: Exploring the conceptualizations of hospice patients and family as a single unit of care." *Journal of Hospice and Palliative Nursing* 13, no. 6 (2011): 419–425.

Neitzke, Gerald and others. "Göttinger Thesen zur gesetzlichen Regelung des Umgangs mit Patientenverfügung und Vorsorgevollmacht." *Ethik in der Medizin* 18 no. 2 (2006): 192–194.

Oddie Graham. "Killing and letting-die: Bare differences and clear differences." *Philosophical Studies* 88, no.3 (1997): 267-287.

Olick, Robert S. "On the Scope and Limits of Advance Directives and Prospective Autonomy." In *Advance Directives*, edited by Peter Lack and others, 53-72. New York: Springer, 2014.

Owens, John. "Creating an Impersonal NHS? Personalization, Choice and the Erosion of Intimacy." *Health Expectations* 18, no. 1 (2015): 22-31.

Parfit, Derek. *Reasons and Persons*. Oxford: Oxford University Press, 1984.

Pennec, Sophie and others. "End-of-life medical decisions in France: a death certificate follow-up survey 5 years after the 2005 act of parliament on patients' rights and end of life." *BMC Palliative Care* 3, no. 11 (2012): 25.

Pereira, André D. "Living will and health care proxy–the Portuguese legal situation" *Medicine and Law* 32, no. 4 (2013): 497–502.

Pereira, Ray. "Human handicap and self-determination: compassion and insensibility in the Vincent Humbert case." *História, Ciências, Saúde-Manguinhos* 14, no.1 (2007): 119-134.

Perrett, Royw W. "Killing, letting die and the bare difference argument." *Bioethics* 10, no. 2 (1996): 131-139.

Pope Thaddeus. "The best interest standard: both guide and limit to medical decision making on behalf of incapacitated patients." *The Journal of Clinical Ethics* 22, no. 2 (2011): 134-138.

Prendergast, Thomas J. "Advance Care Planning: Pitfalls, Progress, Promise." *Critical Care Medicine* 29, no. 2 Suppl (2001): N34–N39.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Deciding to Forego Life-Sustaining Treatment.* Washington: U.S. Government Printing Office, 1983

Rini, Christine and others. "Interpersonal Influences on Patient's Surgical Decision Making: The Role of Close Others." *Journal of Behavioral Medicine* 34, no. 5 (2011): 396–407.

Robin L. Fainsinger, and others. "The cultural differences in perceived value of disclosure and cognition: Spain and Canada." *Journal of Palliative Care* 19, no. 1 (2003): 43–48.

Rossi, Paolo G. and others. "Dying of cancer in Italy: impact on family and caregiver. The Italian Survey of Dying of Cancer." *Journal of Epidemiology and Community Health* 61, no. 6 (2007): 547-554.

Rousseau, Jean J. *Du contrat social*. Paris, Flammarion, 2001. [original work published 1762].

Shickle, Derren. "The Mental Capacity Act 2005." *Clinical Medicine* 6, no. 2 (2006): 169–173.

Schroder, Christina and others. "Representative survey of German people concerning enlightenment and patient directive in a case of terminal illness." *Psychotherapie, Psychosomatik, medizinische Psychologie* 52, no.5 (2002): 236–243.

Sokalska Maria E. "Implementation of the Convention in Central Europe: the Case of Poland." In *Health law, Human Rights and the Biomedicine Conention: essays in honour of Henrietee Roscam Abbing*, edited by Gevers Sjef K.L. and others, 255-268. Leiden: David Adams, 2005.

Steering Committee on Bioethics, (prepared by Hacpille Lucie) "Medical decisions in end-of- life situations and the ethical implications of the available options" http://www.coe.int/t/dg3/healthbioethic/Activities/09_End%20of%20Life/CDBI_2008_30%20Hacpille%20e.pdf

Steinbock, Bonnie *The Oxford handbook of Bioethics.* Oxford: Oxford University Press, 2009.

Thom David H, and Babatunde Campbell. "Patient-physician trust: an exploratory study." *The Journal of Family Practice* 44, no. 2 (1997): 169-176.

Thom David H, and others. "Physician trust in the patient: development and validation of a new measure." *Annals of Family Medicine* 9, no. 2 (2011): 148-54.

Thomas, Carol. "Companions through cancer: The care given by informal carers in cancer contexts." *Social Science and Medicine* 54, no. 4 (2002): 529–544.

Thomaska, David C. "Proposing a new agenda: bioethics and international human rights." *Cambridge Quarterly of Healthcare Ethics : CQ : the International Journal of Healthcare Ethics Committees* 10, no. 3 (2001): 299-310.

Teno, Joan and others. "Advance Directives for Seriously Ill Hospitalized Patients: Effectiveness with the Patient Self-determination Act and the SUPPORT Inter- vention. SUPPORT Investigators. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment." *Journal of the American Geriatrics Society* 45, no. 4 (1997): 500–507.

Toro, L. Blanco and others. "Perfil del cuidador principal del enfermo en situación terminal y análisis del riesgo de desarrollar duelo patológico." *Medicina Paliativa* 14, no. 3 (2007): 1-5.

Whiting, Raymond A. "A natural Right to die." *Omega (Westport)* 32, no. 1 (1995-1996): 11-26.

Wiesing, Urban and others. "A new law on advance directives in Germany." *Journal of Medical Ethics* 36, no. 12 (2010): 779–783.

Witting, Marsha N. and others. “Stability of preferences for end-of-life treatment after 3 years of follow-up: the Johns Hopkins Precursors Study.” *Schistosomiasis* 168, no. 19 (2008): 2125-2130.

Zerwekh, Joyce V. *Nursing Care at the End of Life Palliative Care for Patients and Families.* Philadelphia: F. A. Davis Company, 2005.

Chapter 3: Advance Directives in Italy: ethical and law comparative approaches

Abstract:

The current Italian ethical and legal situation regarding end-of-life decisions is analyzed because the Italian situation regarding end-of-life is quite complex and controversial. The current position of the Italian bioethical and medical communities and of the national jurisprudence are exposed since in Italy there is a lack of *ad hoc* law governing end-of-life situations.

The Italian Bill no. 2350 '*Provisions relating to therapeutic alliance, informed consent and advance directives for treatments*' – approved in different texts in 2009 by the Senate and in 2011 by the Chamber of Deputies – is criticized by taking into consideration the outcomes of the previous part of this scientific work. Similarities and differences between Bill no. 2350 and the eight proposal-bills of the new legislation are also highlighted. Since this bill protects the ethical principle of sanctity of life, it grants advance directives advisory force, limits their application in time and does not allow the validity of oral declarations. This political decision limits patient autonomy. Furthermore, there are doubts about the constitutionality of this bill, especially with respect to articles 2, 13 and 32 of the Italian Constitution, related to the right of self-determination.

Moreover, the judicial interpretation of amended articles 404-413 of the Italian Civil Code – which introduced to Italy the legal role of the support guardian (*amministratore di sostegno*) – is examined. Italian judges apply these articles to fill the absence in the Italian legal system regarding the role of the legal proxy in the dying process. Although Italy is not part of the common law legal system – and therefore the principle of precedent is not applied – the interpretation of these articles is considered by national judges as a manoeuvre to underline the role of the legal proxy in end-of-life situations and to safeguard patient autonomy.

The goal of it is to analyze the Italian bill no. 2350 through a comparative legal approach, especially by comparing it with the French, German and English models. In addition, the protection of the right to self-determination by the Italian jurisprudence are pointed out.

1. The current situation in Italy: the position of the bioethical and medical communities

Although Italy does not have a specific Law governing advance directives, Bill 2350 "*Provisions relating to therapeutic alliance, informed consent and advance directives for treatments*" recognizes the importance of ADs in the Italian legal system. However, similarities and differences between the new proposal-bills and article 6 of bill 2350 are highlighted (e.g., see Sect. 1.1.3.). As in France with the previous law of 2005 (Pereira 2007, Dupont 2005)[155], this bill has been a political reaction of a case-law, that of Eluana Englaro. Its goal has been the 'protection of life' (De Luca et al. 2012);[156] thus, risk coming by the implementation of AD has been highlighted.

After examining the current position of the Italian bioethical and medical communities, the Italian Bill no. 2350 has been critiqued according to the results coming from the previous part of this thesis. The juridical interpretation of amended articles 404–413 of the Italian Civil Code (C.C.), introduced by law no. 6 of 9 January 2004, is examined. The investigation of the documents published by the Italian bioethical community reveals the change of approach regarding end-of-life decisions: from a paternalist one to a

[155] The *Loi relative aux droits des malades et à la fin de vie,* law no. 2005-370 of 22 April 2005 has been considered as a political reaction of the case-law of *Vincent Humbert*. (Pereira 2007, and Dupont 2005)

[156] The phrase 'protection of life' appears three times, where two of them in the main inspired principles of this bill (article 1, section 1, let A and C).

liberal approach. Moreover, the juridical interpretation of articles 404–413 C.C. shows how judges concretely protect patient autonomy, sometimes by going beyond the textual interpretation of these articles.

The current position of the Italian bioethical and medical communities are exposed. The interpretation of the different legal concepts used – such as advance directives or execution of them in case of permanent unconsciousness without cortical and subcortical brain activity – are analyzed. In addition, the correct interpretation of the rules established in the Convention on the Rights of Persons with Disabilities are included. The Italian bioethical debate regarding withdrawing alimentation and hydration is exposed and the rigidity forms established for the validity of advance directives are criticized. Further, the strict formalities established for the nomination or the substitution of the surrogate, the possibility to nominate only one surrogate, the uncertainty of sanctions in case of violation of rules recognized in this bill, and the political decision made in case of absence of patient's surrogate show the lack of protection of patient autonomy. Moreover, the non-existence of an impartial authority to resolve disagreement between surrogate and physicians or to control surrogate's activity it further demonstrates the absence of safeguarding of patient's right to self-determination. The juridical interpretation of amended articles 404–413 C.C. is investigated. Italian judges have applied these articles to fill the gap in the legal system regarding the role of the legal proxy in the dying process, sometimes by going beyond the literal and teleological interpretation of them.

Before analyzing the Bill no. 2350 and the eight new proposal-bills deposited in the parliamentary commissions, since there is a lack of *ad hoc* law, it is important to examine the position of the Italian jurisprudence, of the bioethical community and of the medical community. Currently, from a strict Italian legal point of view, an AD should be considered as a unilateral act – declaration of intent (Canestrari 2003) – which produces legal effects in the non-pecuniary individual sphere: its aim is to (consent to or to) reject future medical treatment in case of an agent's incapacity. ADs are an application of

the right to self-determination recognized by the Italian Constitutional Court (Cost. C. 15 December 2008, no. 438) from the combination of Articles 2, 13 and 32, section 2 of the Italian Constitution. As the Constitutional Court has underlined, the right to self-determination differs from the right to health – guaranteed by Article 32, section 1 – due to the fact that it is broader and involves patient autonomy.

In Italy, ADs can be made only by people with full competency. Furthermore, simple opinions or declarations that do not aim to produce a legal effect on relationships with physicians must not be considered (C. Cass. 23 February 2007 no. 4211). Physicians must pay close attention to patients' medical declarations, because on one hand they should not take into consideration simple opinions, but on the other, they must be aware that patients' preferences change during the course of a disease (Carmel and Mutran 1999, Berger 1998, Marion et al. 1994). However, in case of patients with dementia, previous ADs should remain in force, because critical interests deserve priority over experiential interests.[157]

Finally, the ruling no. 4211 of 23 February 2007 of the High Court of Cassation should be mentioned. This ruling states that in case of a risk of

[157] According to Dworkin, there should be a difference between critical interest, those that determine personal goal of life, and experiential interest, those that entail experience pleasure, pain, happiness or other feeling (Dworkin 1986). In cases of patients with dementia, empirical research has shown that advance directives are considered valid, but their effectiveness seems marginal (de Boer et al. 2010).

death the patient's ruling must be expressed, unequivocal, concrete and informed. Thus, an abstract, ideological refusal where the agent does not envisage medical treatment in the near future cannot be followed because this refusal is based on an *ex ante* and not *ex post* ruling.[158] This is an application of the principle *in dubio pro vita.* This ruling has been much criticized, because the application of this theory leaves room for physicians' paternalism, in contrast with the spirit of the right to self-determination that inspires the Italian Constitution.[159]

The Italian National Bioethics Committee (NBC) has underlined the significance of advance directives in several documents, which are: *Bioethical issues regarding end-of-life* (1995), *Advance directives* (2003), and *Dementia and Alzheimer: ethical consideration* (2014).

[158] A typical example is the case of Jehovah's Witnesses' ban on blood transfusion. Following the argumentation of this decision, which is based on the interpretation of Article 40 of the Code of Medical Ethics, even in the presence of a prior express refusal a doctor, faced with an unexpected and unpredictable worsening of the patient's condition in a combination of circumstances that do not permit the inspection of actual wishes and if it is necessary to save the patient's life, could consider certain or highly probable that the prior rejection of therapy is no longer valid.

[159] More criticisms of the decision of the High Court of Cassation no. 4211 of 23 February 2007 can be found in the paper of Masoni, where the author criticizes the Court's decision by highlighting the contrast with Article 32 of the Italian Constitution, Article 9 of the Convention of Oviedo, Article 38 of the Italian Medical Ethic Code and with the Advice given by the Italian National Committee of Bioethics on December 2003 (Masoni 2009).

Among them, the advice *Advance Directives* is entirely dedicated to this issue. Through this document, the NBC has recognized that ADs are not just an instrument for the legitimation of the medical treatment, but also a fundamental human right. In addition, ADs are important for the implementation of the theory of informed consent: ADs are seen as instrument to make still possible the personal relationship between patient and physicians, although the patient is unconscious. It follows that the unconscious patient will be treated as a person according to his/her wellbeing and not as a human body to cure.

Although the significance of ADs has been underlined, in the advice given in 2003, the NBC has adopted quite a conservative approach. It should be mentioned that this conservative approach has been codified by the Bill no. 2350 and the proposal-bill 2229, and then by the Italian Code of Medical Ethics of May 2014. From the first paragraph, the NBC has highlighted that ADs shall be in written form, are time-limited, and can be expressed only after the physician has informed the citizen with all the information needed. Moreover, the physician's professional autonomy has been emphasized in several paragraphs. Therefore, *"directives contrary to law, norms of good clinical practice, or medical deontology"* shall not be applied (p. 9).

The NBC has established that there exists an ethical consensus that ADs are an important instrument in the patient-physician trust; nevertheless, there exists a contrast between law and medical deontology, in addition to doubts related to the structure of ADs and the modality of their execution. The main problem relates to their ambiguity, which – according to the advice *Advance Directives* – can never be excluded, neither in cases that these documents were written after the diagnosis of the disease since the same disease might have different treatments.

Therefore, according to NBC (2003), ADs should not have legally-binding force. This is in accordance with article 9 of Oviedo Convention and with section 62 of its Explanatory Report. This is why the final version of it substituted the adjective *"decisive"* with *"previous expressed wishes … shall be*

taken into consideration". It follows that a patient's previous wishes should not be considered as (simple) orientations. In addition, physician should have convincing arguments in order to not follow a patient's directives. However, physicians are not legally bound to follow them.

With the aim to decrease the problem derived from the ambiguity of ADs, the role of the surrogate has been highlighted. Nevertheless, in the advice of 2003, it is written that currently this role has been *"carried out, or should be carry out"* by the patient's family (p.8). Moreover, although the surrogate's opinion has an ethical justification since the patient has given his/her power to the surrogate, it is inappropriate to attribute legally binding-force to the surrogate's opinion.

The problem related to ANH has been highlighted as well. In the advice of 2003, the committee has not taken an official position regarding this issue (a position that has been taken in the document *Alimentation and the nutrition and hydration for patients in a persistent vegetative state* in 2005), however, it has highlighted the ethical and medical division regarding this issue. While a group of bioethicians consider the withdrawal of ANH possible, another group considers it as basic care and therefore punishing the withdrawal of ANH (e.g., see Sect. 3.2.1.).

It should be noted that although the advice of 2003 is quite conservative, in 1993, in the document *Bioethical issues regarding end-of-life*, the NBC considered ADs as "*orientation documents"*, raised doubts on the ethical principle of prospective autonomy (e.g., see Sect. 1.3.), and stated that it is deontologically inadmissible to exclude some types of treatments through ADs (by including both 'living wills' or 'surrogate will').

But, in 2014, in its advice *Dementia and Alzheimer: ethical consideration*, the NBC has taken quite a liberal approach. In this document – approved by all the members in unanimity – it is stated that in cases of dementia and Alzheimer's disease, *"it is recommendable that the patient use advance directives"* (p. 22). The ethical principle of prospective autonomy is seen not only as an instrument to legitimize medical treatment, but also as an

act that gives substantial protection to patient rights. Since the citizen has decided to write ADs, it derives that he/she has personally and fully assumed and accepted the risks of uncertainty, contingently, and precarious in both ethical and legal perspectives.

Although the advice of 2014 does not specify the force of ADs (legally-binding force or advisory power), for the first time the physician or to the legal proxy is given the authority to decide about the power of the patient's previously expressed wishes. Until 2014, the NBC has given the complete authority to decide on the execution of ADs only to the medical community.

So, originally taking a completely conservative approach in 1993, the NBC, in 2014, has underlined the significance of ADs. While in 1993, the NBC did not accept the ethical principle of prospective autonomy and considered ADs, as well as giving to the physician the power to decide on their execution, as inadmissible from a deontological approach; in 2014, however, the NBC has recommended the application of ADs and has given to physicians *or* legal proxy the authority to decide the significance of previously expressed wishes by the patient.

Analyzing the position of the medical community, it should be said that the two main medical societies in Italy are: the Italian Society of Anaesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) and the Italian National Federation of Associations of Physicians and Dentists (FNOMCeO). The two main documents regarding ADs published by the SIAARTI are the guidelines *"End-of-life and the intensivist: SIAARTI recommendations on the management of the dying patient"* (2006) and the advice regarding *"End-of-life, vegetative state, nutrition and hydration"* (2009). In both these documents the SIAARTI distinguishes between "sick person" and "dying patient". Nevertheless, both these guidelines lack a temporary condition regarding the identification of the "dying patient". The SIAARTI could have applied the guidelines established by the General Medical Council in UK (2010) that states that the palliative care should not start before twelve months from the predictable death of the patient.

According to SIAARTI, in the case of a "sick person", medicine's goal is to prolong the patient's life with a good quality of life that the patient himself/herself considers acceptable; however, when caring for the "dying patient", the aim of medicine is to grant the patient a respectable quality of life during his/her remaining lifetime. In the guidelines of 2006, the SIAARTI emphasized the importance of communication between the medical staff and the patient, or his/her family in the case of an unconscious patient. This approach is in coherence with the concept of *transitional palliative care* (e.g., see Sect. 2.1.3.).

Moreover, in the case of 'living will', the SIAARTI has made a distinction according to the time that these documents were written. In case that previously expressed wishes have been written after the patient has received clear medical and clinical information regarding his/her diagnosis and prognosis, therefore within a program of medical advance planning, the medical staff has to respect these wishes. In other cases, when a 'living will' was written a long time before its execution and without having clear information regarding the consequences of the concrete disease, and therefore the previous expressed wishes are written in general terms, then *"the decision of the doctor to respect or ignore the patient's statement is heavily influenced by his judgment of the appropriateness of withholding or withdrawal intensive care"* (p. 942).

In 2009, the SIAARTI stated – in accordance with FNOMCeO (2009) – that the Italian legislator should establish an *ad hoc* law ruling ADs by highlighting the role of the surrogate. In addition, these documents can contain only the physician's act of *non facere* and should be time-limited. Furthermore, ADs should be written within a program of advance care planning, and the patient should be aware of the medical and clinical consequences of his/her disease and treatment. Moreover, ANH is considered a medical treatment (e.g., see Sect. 3.2.1.).

This approach has been confirmed in 2013, with the last document focuses on end-of-life care. Although the focal point of this document is

intensive and palliative care, the significance of ADs and patient-physician trust are pointed out. The importance of this document stands on the fact that ADs and care planning are considered not only in case of patient with terminal illness, but also in the field of neurology.

In accordance with the document published in 2006, the active role of the patient, and therefore the patient-physician dialogue and communication have been highlighted. In addition, the role of the legal proxies (surrogate or guardian), especially in case of dementia, have been underlined. It should be noted that in case of patient with dementia, on 2014, the NBC has applied the same approach of SIAARTI in 2013.

However, the documents of SIAARTI (2006, 2009, and 2013) have been criticized since according to them ADs should be taken consideration and should not have legally binding force, especially if these directives were stated outside a care planning discussed with physicians.

In 2014, the FNOMCeO published the Code of Medical Ethics. In Italy, physicians must be part of this federation; otherwise they cannot exercise the medical profession. In case of infringements of its norms, the FNOMCeO can apply disciplinary sanctions (article 2). Article 38 of the new Italian Code of Medical Ethics states that ADs should be in writing and that these future directives are not legally binding. Moreover, physicians have the power to verify not only their clinical consistency, but also their logical consistency. It remains unspecified what steps this verification entails. Furthermore, physicians and legal proxies must seek the patient's best interest rather than follow the patient's wishes. The article's paternalism is inherent in its limitation of ADs to written statements: living wills could be limited to written form, but not ADs in general, which form a broader concept of statements concerning individual preferences. Moreover, ADs should be legally binding and not only of advisory force. In addition, physicians should have only the power to ascertain clinical consistency and not also to verify the logical consistency of a living will. Further, physicians and legal proxies should

consult the patient's wishes and only act according to the patient's best interest if those wishes are unclear.

Although the FNOMCeO has adopted in 2014 a conservative approach, it should be mentioned that the previous version of the Code of Medical Ethics, the one of 2006, was more liberal. In the case of an unconscious patient, *"the physician must take into account the previous choices expressed in a clear and documented manner"* (article 38, section 3). This version is similar to article 9 of the Oviedo Convention (e.g., see Sect. 2.1.). The main criticisms of this section were related to the fact that ADs were delineated with 'living will' and ADs were connected with the patient's choices and not with the patient's wishes or will. In addition, the "*previous choices"* should have been expressed in a clear manner, which in practice is quite rare. Moreover, the role of surrogate (or other legal proxies) was not mentioned. Furthermore, there was a lack of procedure regarding people who are incapable of writing.

Concluding, the withdrawal of medical treatment is common, also in Italy (Bertolini and Boffelli 2007). Therefore, the intervention of the Italian legislator has been asked for not only by the jurisprudence, but also by the bioethical and medical community. Both these communities have underlined the importance of clear legal norms ruling end-of-life decisions. According to them, ADs will emphasize patient autonomy and are in accordance with physician's duty to care. In addition to the safeguard of patient autonomy, both these communities have asked the parliament for the protection of the physician's consciousness objection (NBC 2012, FNOMCeO 2009). The consciousness objection or the right of conscience is a constitutional right guaranteed to physicians as human beings rather than as medical experts. Nevertheless, the medical consciousness objection must be strictly connected with the protection of other fundamental constitutional rights (NBC 2012).

2. The Italian bill on advance directives: the problem of their limitation

Article 3 of Bill No. 2350 recognizes the importance of advance directives that can be executed only in case that the agent is permanently incapable, and lacks cortical and subcortical brain activity. According to the Convention on the Rights of Persons with Disabilities, alimentation and hydration must be kept until the last moment of life; except in cases where these treatments do not benefit the patient. Further, medical advance declarations have an advisory force.

This Bill states that ADs – as in France before the law 348 of March 2015 (article 1111-11 *Code de la Santé Publique*)[160] – have no legally-binding force[161]. This political choice could be explained only by the considerable influence of the traditional Catholic approach within the Italian political parties. Catholicism has been considered as the "key factor explaining the

[160] The previous French law of 2005– as in Italy – the so-called *Leonetti* Law came as a reaction to the case-law of *Vincent Humbert.* This is the main reason why the French law focuses on fixing "a clear framework for legal or illegal medical practices at the end-of-life, rather than a framework for respecting patients' autonomy" (Horn 2014). As Leonetti stated in 2005, the aim of the Law is to "ease doctors' feelings of guilt" (Assamblee Nationale 2008). The French Parliament of March 2015 has changed this policy. Currently, in France, ADs are legally binding. This has been presumed by the use of the verb *imposer* (impose). However, a degree of the Council of State will set the condition for the validity, confidentiality and conservation of these documents.

[161] All new proposals – expect proposal 2229 – establish the legally-binding force of ADs.

more pro-life profile" (Menaca et al. 2012) of Italian end-of-life decision-making and with the perception of a high level of tolerance of pain within the Italian medical community.[162]

Article 3, section 1 states that ADs can be written only by fully competent agents[163]. The focus on ADs is a direct result of the fact that individual autonomy – which, in the Western countries, is based on the neo-liberal and utilitarian perspective (Woods 2007) – requires as a pre-condition the mental capacity, which in palliative care can be reduced or altered (Department of Health 2008). This is why "death should become an explicit discussion point when patients are likely to die within 12 months" (Gardiner et al. 2011). In addition, the patient's participation in end-of-life decisions during palliative care becomes more tensions because two different preferences – wanting control over life and wanting to be cared for – contrast between them (Seymour 2004).

There is a difference between the legal concept of "competency" and the clinical and ethical concept of "capacity". To be competent is to have sufficient mental capacity to rationality fulfil tasks. This is a matter of fact, not of law. Moreover, the capacity is "task specific so individuals may have the capacity to

[162] In Italy, terminal sedation is more accepted than euthanasia or physician-assisted suicide and is more frequently implemented than in other European countries. (Catania et al. 2008, and Miccinesi et al. 2006).

[163] It should be noted that all the new proposals – expect proposal 1298 – establish the same principle. The proposal 1298 states that citizens over 16 years old can also write an AD (article 3, section 1).

make some decisions but not others" (British Medical Association 2007). Thus, different actions require different levels of mental capacity.

The Italian Bill requires that ADs can be written only after complete medical and clinical information has been given[164]. This has raised several problems because it is quite impossible to predict all the possible diseases that entail unconsciousness and all medical treatments that could be used in these cases (Holley 2005). Therefore, this legal requirement becomes more of a formal requirement – which increases bureaucracy – with no applicability to medical practice. The previous discussion with the physician could be appreciated in case of chronic and degenerative illnesses. In case that the new Italian law will emphasize this rule, this requires training program for doctors and other health-care professionals. This could entail further costs for the public budget.

The previous contact with the physician emphasises the concept of relational autonomy (Epstein 2013). The key for the promotion of patient-physician trust is the partnership between them, which presupposes a relationship between patient and physician (e.g., see Sect. 1.2.). It follows that 'living wills' written in rehabilitation centers – where the patients have had

[164] This formality has been established in proposal 2229 (article 3, section 1 and article 4, section 1). Instead, the proposal 443 establishes the need of the advice of a Noter and that of the physician (article 13); the proposal 1298 requires the presence of two witnesses (article 3, section 7); and the proposal 2264 states that the ADs should be written in front of the public employer of the Municipality Register of Advance Directives (article 2, section 3).

several conversations with varies physicians – are more precise regarding the future concrete medical condition. This model has recently been highlighted in the *Guide* published by the Council of Europe on May 2014. Differently form the model adopted in the USA, in Europe, patient autonomy is not the only value that the bioethical community considers fundamental. Other values – such as 'solidarity' (Manson and Laurie 2011) and physician autonomy[165] – have been highlighted as well.

Also, this policy is in harmony with the individualist model of autonomy, which considers autonomy model as a 'self-sufficient decision-making' factor. Nevertheless, as the scholars of ethics or care have noted, the role of the physician in these two models has changed. While in the relational autonomy the patient-physician trust is highlighted, in the individualistic model of autonomy, physicians should only give medical information and not interfere with the individual's decision- making process (Walter and Ross 2014).

The Bill underlines the fact that ADs cannot include requests for crimes such as homicide (article 575 P.C.), homicide by request of the victim (article 579 P.C.) or aiding or incitement suicide (article 580 P.C.).[166] This policy has

[165] Doctor autonomy is considered so important in Europe that the Portuguese legislator of 2012 has codified the medical objection in the law ruling ADs (article 9 , Law no. 25 of 16 July 2012)

[166] It should be noted that contrary to Article 1, section 1, paragraph C), in Article 3 the phrase "any kind of euthanasia" – whose interpretation could be ambiguous – does not appear.

been repeated identically in the new proposal 2229 (article 3, section 3) and proposal 1432 (article 1, section 1, let. e)[167]. This is in harmony with the other European Legislation – except countries that allow euthanasia or PAS, such as the Netherlands, Belgium and Luxemburg (and to some extent, Germany) (see *supra* note 95) [168] – where ADs can impose on physicians a legal obligation of "not acting" or to withdraw medical treatment, but cannot include an obligation to act.

According to this article the only medical treatment that can be rejected through ADs are experimental or disproportionate treatments[169]. Hence, any medical treatment that prolongs life could be considered as proportionate (Bonsignore et al. 2012). The possibility of futile treatment is really low. This

[167] The proposal 1432 prohibits euthanasia, assistance and helping in suicide.

[168] However, it should be underlined that recently the German High Court (decision of 25th June 2010) has gone beyond the traditional legal distinction of act and omission. By taking into account the ethical principle of no distinction between 'active' and 'passive' euthanasia and the legal principle of unity of the legal system – not only in a horizontal approach between civil and criminal law, but also in vertical approach between constitutional principle and law – has stated that it is lawful the case of detachment of probe from the health care proxy. The German High Court, as the European Court of Human Rights in the famous case Pretty v United Kingdom, justifies this decision based on Article 1 (*human dignity*) and Article 2 (*personal freedom*) of the German Constitution. Nevertheless, in this decision, the High Court précises that active euthanasia and any kind of act that hastens death without palliative care are illegal.

[169] All the proposals – except proposals 13 and 2229 – do not establish any limit to the object of ADs. While proposal 2229 recognizes the same limitation of the proposal 2350 (article 3, section 4), the proposal 13 states that medical treatments that protect patient's personal dignity cannot be withdrawn (article 19, section 2).

is in contrast with the newer model of medicine where patients' autonomy and well-being is the core of medical decisions (e.g., see Sect. 1.1.).

Moreover, substantial criticism has been raised of the last section of article 3. According to it, ADs are executive only in case of permanent incapacity without cortical and subcortical brain activity[170], which must be certified by a medical commission composed of an anaesthetist, a neurologist, a specialist of the pathology concerned and the physician in charge of the patient[171]. The amended Bill from the Chamber of Deputies removed the role of coroner from the commission.

Before criticizing this norm from a legal point of view, several concepts – such as brain activity, comma, and vegetative state – should be explained from a medical and ethical prospective. As it is well known, brain is divided in

[170] All the proposals – except proposals 1432 and 2229 – recognize the patient's incapacity as the only requirement for the execution of ADs. This policy is in harmony with the ethical principle of patient autonomy and with the ethical definition recognized by the majority of bioethicist. While proposal 2229 establishes the same requirement of proposal 2350 (article 3, section 1), the proposal 1432 states that prior medical instructions must be applied only in case of irreversible incapacity.

[171] Within the new proposals, only four out of eight establish an internal medical collegium to check the patient's incapacity. Proposals 5 (article 10, section 2) and 443 (article 14, section 2) compose this team with three physicians: the neurologist, the psychiatrist and with a physician specialized in the patient's pathology. The proposal 1142 (article 11, section 2) also includes the physician in charge. The proposal 2229 (article 3, section 5) states that the medical commission is composed of an anesthetist, a neurologist, a specialist of the pathology concerned and the physician in charge of the patient.

three main parts: the cortex (responsible for our human intellectual existence), the thalamus (regulates our animal existence), and the brain steam (controls our vegetative functions including breathing). Consciousness is the most critical moral standard for human personhood (Cranford and Smith 1987); it follows that the whole status of the person in vegetative state is in doubt. For some neurologists and philosophers, that give a high importance to the consciousness, death should be connected with the idea of death of the cerebral cortex (Zullo 2010). However, Italy – like the other western countries – has applied the legal definition coming from the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research of 1981, which is based on the Havard's study of 1968. Therefore, the person is dead when it has been certified that the all the functions of the encephalon are irreversible (article 1 of the Italian law no. 578 of 29 December 1993).

Differently from the other types of cells, brain cells, once destroyed cannot be replaced. When a person suffers severe brain damage, he or she could end up in a state of coma. From the late 1950s, the medical community generally distinguishes four degrees of coma: *coma vigile* (blurring of consciousness and intellect), *coma type* (loss of relative functions), *coma carus* (loss of vegetative functions), and *coma depassé* (loss of all functions) (Mollarei and Goulon 1959). It should be noted that the degree of coma does not change because once the oxygen supply is restored; the patient's condition is static (Manson and Laurie 2011).

Regarding the definition of vegetative state – except problems highlighted above (Sect. 1.5.1.) – it should be highlighted that the word 'vegetative' fails to define the degree of brain damage involved. Moreover, the concept of 'persistent vegetative state' has a semantic incoherency. From a semantic prospective, a persistent state is a state that persists until it is relieved; it follows that the patient does not have a possibility of recovery. This shows the medical and semantic contradiction because while from a semantic meaning of 'persistent' the patient does not have a possibility of

recovery, from a medical prospective, the patient in a persistent vegetative state does have a possibility of recovery.

From a legal point of view, this section has had three major criticisms. First of all, according to Italian Society for Anastasia Analgesia Resuscitation and Intensive Care (2011), permanent unconsciousness without cortical and subcortical brain activity is not a matter of nosology, but constitutes brain death (Italian Society for Anastasia Analgesia Resuscitation and Intensive Care 2011). Therefore, all treatments in this case are considered futile. Secondly, the fact that ADs take effect only in case of permanent incapacity could entail problems in case of Jehovah Witness patients who reject blood transfusion. In their case, incapacity is not permanent, but temporary. Thirdly, in case of acceptance of this 'new' legal definition, the commission that confirms the patient's incapacity must be include a coroner because this is the medical branch dedicated to the process of verifying the causes of death (De Luca et al. 2012). Moreover, the physician in charge of the patient should not be part of this proceeding because – as the *Guide on the decision-making process regarding medical treatment in end-of-life situations* of May 2014 (p. 16) has stated – the assessment of the patient's incapacity should be assigned by an impartial assessor.

If the Italian Legislator were to follow the German model – where advance directives are valid independently of the disease's stage (article

1901a, section 3)[172] – procedural rules about the composition of the medical commission and practical problems that this 'new' legal definition entails would be avoided.

2.1. The problem of withdrawing alimentation and hydration through advance directives

The Italian Bill states that, according to the Convention on the Rights of Persons with Disabilities, alimentation and hydration must be provided until the last moment of life, except in cases where these treatments do not benefit the patient.[173] This phrase has been repeated in the proposal from Ms. Roccella and others on 26 March 2014 (article 3, section 4). The problems regarding the withdrawing of alimentation and hydration through ADs have been an object of the Italian political debate. Therefore, five out of eight new proposals mention it directly[174]. The debate regarding ANH has been object also of the

[172] In Germany, an opposing Bill proposed by the conservative parties, *limited the application of advance directives to illnesses with an "irreversible fatal progression"*. However, the German Legislator did not follow this version, but rather suggestions from the German Bioethical Community (Neitzke 2006).

[173] The phrase *"do not benefit"* must be considered in medically objective way. This is why Article 3, section 4 states that withdrawing artificial nutrition or hydration cannot *"form part of the advance directive".*

[174] In specific proposal 443 states that parental alimentation and hydration is not considered as futile treatment. The proposal 1298 (article 3, section 1, let. c)) and

Guide on the decision-making process regarding medical treatment in end-of-life situations of May 2014 (e.g., see Sect. 2.1.3.).

Before analyzing the concept of ANH from a legal perspective, these norms should be explained by applying medical and ethical approaches. Within the cases of artificial nutrition, it should be distinguished between nasogastric feeding and gastrostomy feeding. While in the first case the tube passes through the nose and it remains for a short term, in case of gastrostomy, the tube pass through the abdomen. This difference is important because the entire bioethical community accepts the gastrostomy feeding as medical treatment, but some doubts remain regarding the definition of nasogastric feeding as such. Nevertheless, the community recognizes the nasogastric feeding as a general medical management (Hoppe and Miola).

Moreover, the distinction between omission and action might raise some ethical problems. In addition to what has been written above (Sect. 2.1.3.), in Italy, the National Bioethics Committee has underlined this issue. In the advice of 2008, *Conscious withholding or withdrawing medical treatments in the patient-physician relationship*, the NBC, instead of taking an official position, highlighted the division among its members. Some members

the proposal 2229 (article 2, section 1, let. b)), after legally defying the notion of ADs, states the interested party can withdraw artificial alimentation and hydration or alimentation and hydration given by third parties through ADs. The proposal 1432 establishes that every competent person can withhold or withdraw, even artificial nutrition, through ADs (article 1, section 1, let. f)).

considered – from an ethical perspective – the withdrawal of medical treatments as active euthanasia, while others make a clear distinction between these two types of medical practice. The fact that the NBC has not taken a clear position regarding this issue has raised doubts about its role as an advisory body to the Government: twelve of its members have written different opinions.

The fact that in Italy there is not an ethical consensus regarding the withdrawal of medical treatments is considered very problematic. In USA, in 2008, the American College of Critical Care (Truog et al. 2008) has established a consensual statement regarding the withdrawal of life-sustainment treatments. These three principles are: 1) Withholding and withdrawing life support are equivalent; 2) there is a distinction between killing and allowing to die; and 3) the doctrine of "double effect" (Sulmasy 2000, Quill 1997, Quill et al. 1993).

It should be noted that although clinicians are psychologically more comfortable withholding treatments than withdrawing them, since in case of withholding there is a passive act, both philosophical and legal analyses have emphasized that physicians should make no distinction between withholding or withdrawing medical treatments (Meisel 1991). The medical staff should always base their decisions on an assessment of its benefits versus burdens and the preferences of the patient: it follows that not initiating or stopping the medical treatment has the same medical, ethical and legal consequences. Furthermore, sometimes the value of a treatment can only be determined after a trial of therapy. If the medical staff is reluctant to withdraw therapies, they might make a premature decision to withhold medical treatments.

When withholding or withdrawing medical treatments physicians are not killing the patient, they are allowing a patient to not be treatment with unwanted treatments. *Barber v Superior Court* (195 Cal Rptr 484, 486) is the first reported case in which the judge stated that withdrawal of ANH is allowed, and physicians are not criminally liable for following the wishes of the surrogates (Geppert et al. 2011). When treatments have been withdrawn,

care must continue, and it must be noted that while before it was thought that death from dehydration would cause the patient unnecessary suffering, the medical staff has testified that death of dehydration is palliative (Fine 2006). According to the so-called double effect doctrine, there exists a moral distinction between administrating doses of medications that kill the patient *versus* giving them with the intention to give the patient a good quality of life, but with the foreseen consequence of potentially shorting the patient's life.

Continuing with the analysis of the Italian Bill 2350, article 3, section 4 of the Italian Bill 2350 has received a lot of criticism, because other countries do not set limits to the object of advance directives. There are three main criticisms of this section. The first is article 3, section 4 entails an incorrect interpretation of article 25 of the Convention on the Rights of Persons with Disabilities of 13 December 2006 and ratified in Italy by Law no. 18 of 3 March 2009 (Molaschi 2012). Article 25 of this treaty – after recognizing informed consent by people with disabilities in paragraph d) – states in paragraph f) that Parties shall "*prevent discriminatory denial of health care or health services or food and fluids on the basis of disability*". Article 25 of this Convention envisages cases where patients with disabilities ask for medical treatments, not cases when patients refuse them through instructional directives written when they were of sound mind.

Secondly, the Italian Legislator should have used the term 'living wills' and not the general concept of advance directives[175]. According to the British Medical Association, it is the living will – not the broader concept of advance directive as stated in the Italian Bill – that is the formal declaration written by a competent adult conveying his or her wish for any life-prolonging measures to be withheld in circumstances where there is no prospect of recovery (British Medical Association 1995). The same definition has been applied by the Italian National Bioethics Committee (1993).

The third criticism is connected with the definition of nutrition and hydration. From a clinical point of view, nutrition and hydration through a nasogastric tube, percutaneous endoscopic gastrostomy (PEG feeding) or total parenteral nutrition is not considered basic care, because the methods for delivering them are "artificial" (British Medical Association 2007). The same conclusion seems to appear also in the *Guide* of May 2014. Although this document does not aim to take an official position regarding this issue and its goal is the illustration of the public debate regarding the limitation of this kind of care, this guide states that ANH are "given to a patient following a medical

[175] All the proposals – except proposal 13 – have made the same mistake. In specific this mistake has been codified in: proposal 5 (article 1, section 1); proposal 443 (article 1, section 1); proposal 1142 (article 2, section 1); proposal 1298 (article 3, section 1); proposal 1432 (article 1, section 1, let. f)); proposal 2229 (article 3, section 4); and proposal 2264 (article 2, section 1). Instead, proposal 13 (article 18) has adopted the phrase "personal declaration" without limiting them in written declarations.

indication and imply choices concerning medical procedures and devices (perfusion, feeding tubes)" (Council of Europe 2014).

Recently, this has been confirmed by the French *Conseil d'État* in its ruling on 24 June 2014 and from the last ruling of the ECtHR of 5 June 2015. Nevertheless, it should be noted that although the patient is in a minimally conscious state or in vegetative state – which means that the patient cannot exercise his own autonomy directly – it does not justify by itself that doctors should withdraw artificial nutrition and hydration. Physicians must take into consideration not only medical criteria, but also (and mainly) the patient's previous wishes and preferences. In case that there is no 'living will', the surrogate (and the patient's family and relatives) should be involved. Only where the patient's ADs are unknown, the principle in *dubio pro vida* should be applied.

The classification of medical nutrition and hydration is really important, because if it is qualified as basic care, physicians will be liable for homicide (article 575 P.C.) or homicide by request of the victim (article 579 P.C.). The Oleari Commission, formed by the Minister of Health in the year 2000, stated that artificial nutrition and hydration constitutes medical treatment. Also, the Italian Court of Cassation – although without thorough consideration – stated that "artificial nutrition and hydration through nasogastric tube constitutes medical treatment" (C. Cass. 16 October 2007, no. 21748) (e.g. see Sect. 1.5.1.). The same legal reasoning has been adopted by the Italian Council of State in its ruling of 2 September 2014, no. 4460 (par. 36.2). These rulings are based on the international background of the case of Cruzan (Cruzan v Harmon, Missouri Supreme Court, 760 SW2d 408,1988) in the USA and of Bland in the UK (Airedale NHS Trust v. Brand [1993] AC 789).

Even from a medical perspective, artificial nutrition and hydration (ANH) is considered as medical treatment that patients can refuse (American Dietetic Association 2008, Italian Society of Parenteral and enteral nutrition 2007, and A.S.P.E.N. Board of directors 2002). The same result was given by an empirical study conducted in 2009–2011 in the regions of Veneto and

Trentino Alto-Adige, where only 25% of hospital staff considered artificial nutrition and hydration to be basic care (Iasevoli 2013). To support this position, several reasons can be given. First of all, generally, through the tube that transports water and food, drugs are mixed too. Second, a medical prescription is required. Third, for applying ANH, an invasive technique must be used. Fourth, a medical specialization regarding the combination of different types of drugs is needed (SIAARTI 2009).

On the other hand the National Bioethics Committee (2005) in *Alimentation and the nutrition and hydration for patients in a persistent vegetative state* argues that ANH is considered basic care, implying that cases of its withdrawal are punishable as active euthanasia.[176] The same conclusion has been shared by the majority of its members in *Advance Directives* published in 2003. Moreover, the same conclusion was reached by the Commission established by the Ministerial Decree of 12 September 2005, which compared ANH with personal hygiene.

From the legal perspective, article 3, section 4 of the Italian Bill 2350 is not in harmony with articles 3 and 13 of the Italian Constitution and with the interpretation of article 32 given by the Italian Constitutional Court. This section violates the fundamental principle of equity – established in article 3 of the Italian constitution – because it makes a distinction between capable

[176] This document has received much criticism, and thirteen members (out of thirty-five in total) have published a dissenting statement in which artificial alimentation and hydration were considered as medical treatment.

and incapable patients by allowing the right to refuse medical treatment only to the first group (Amato 2010). This means that adults lacking capacity may not be considered a person and all previous wishes may lose validity.

Further, article 13 of the Italian Constitution protects personal freedom in general, which is broader than the right to physical health established in article 32, section 1 of the Italian Constitution (C. Cass. 9 February 2010, no. 2847; C. Cass. 15 September 2008, no. 23676). So, even if ANH could be considered basic care, the right to self-determination, which pervades the Italian Constitution, should always prevail (Maltese 2009), because medical treatment has to protect not only the patient's health but also his or her dignity (C. Cost. 19 June 2002, no. 282).

Furthermore, it should be highlighted that this section is in contradiction with the opinion of several scholars and with a part of the Italian jurisprudence, which consider patient autonomy to be fundamental. The majority of Italian scholars think that the Italian legal system recognizes an unconditional right to refuse medical treatment (Giunta 1997, and Barni et al. 1986). In addition, as mentioned above, a part of the Italian jurisprudence states the priority of the individual right to self-determination over the right to health (C. Cass. 30 September 2008, no. 37077; C. Cass. 23 January 2008, no. 16375; C. Cass. 16 January 2008, no. 11335; C. Cass. 29 May 2002, no. 26446;

C. Cass. 4 July 2005, no. 38852),[177] even if this decision can expose the patient to risk of death (C. Cass. 9 February 2010, no. 2847; C. Cass. 15 September 2008, no. 23676). Thus it must be underlined that the aim of the withdrawal is not to put an end to life, but to discontinue a form of treatment which was refused by the patient directly – through the 'living will' – or indirectly – through the application of the substitute judgment theory.

If one wishes to avoid this classification, there are at least four solutions: the first is the approach taken in the Netherlands, the second is that of the MCA in England and Wales, the third is that of the new French law of March 2015, and the fourth is suggested by bioethicists.

In the Netherlands, feeding a patient through a tube is considered a medical act, which can be halted on the ground of its 'senseless' nature (Kelk 2005). The classification of ANH as a *senseless medical act* under certain conditions avoids the ambiguous legal consequences that come from its classification as basic care or medical treatment. Thus, there is no need for legal qualification, and medical consideration, based on current medical ethical standards, becomes crucial.

The MCA gives the agent the possibility to include in his or her treatment directives the refusal of ANH, but not the refusal of natural

[177] However, there are several Court's rulings that argue that the right to physical and physiological health does not find any limits (C. Cass. 27 March 2001, no. 36519; C. Cass. 9 March 2001, no. 28132).

nutrition and hydration. Therefore, medical nutrition and hydration – which are given to the patient through an artificial tube[178] – can be refused.

The third solution – established in the new French law of March 2015 (article 1110-5-1 CSP) – states directly that artificial nutrition and hydration is a treatment. This rule codifies the ruling of the *Conseil d'État* of June 2014, which distinguished between the intentionally taking of life (PAS and euthanasia) and therapeutic abstention (withdrawing of medical treatment). This ruling is based on the lexical interpretation of the law no. 2005-370 of 22 April 2005 *Loi relative aux droits des malades et à la fin de vie* (e.g., see Sect. 2.1.2.1.).[179] Therefore, in case of withdrawing, this is not a criminal offence and the patient should receive palliative care. There exists a difference between care and treatment (e.g., Sect. 2.1.3.). Although the patient can refuse medical treatment, care should continue since the aim of care is that to alleviate pain and to make the patient feel comfortable, also in the last stage of his or her life.

[178]"Artificial nutrition and hydration refers specifically to those techniques for providing nutrition and hydration that are used to overcome an inability to swallow. It includes the use of a nasogastric tube, percutaneous endoscopic gastrostomy (PEG feeding) and total parenteral nutrition" (British Medical Association, 2007)

[179] The law no. 2005-370 of 22 April 2005 *Loi relative aux droits des malades et à la fin de vie* has modified the previous law no. 2002-303 of 4 march 2002 *Loi relative aux droits des malades et à la qualité du système de santé*. The former law stated that patients have the right to refuse ''a'' treatment without identifying what would have happen if the treatment was considered as a life-sustaining treatments at the end of life. The law of 2005 allows for the refusal of "every" kind of treatment.

The fourth solution – given by various bioethicists, such as Brock – is that physicians should not focus on the abstract quality of artificial nutrition and hydration, but rather answer the question to what extent this treatment benefits a *specific* patient in a *specific* condition (Brock 2009).

3. The Italian Bill on advance directives: their form and content

Article 4 of Italian Bill 2350 details the formalities that ADs must contain. In this article the importance of complete medical and clinical information is re-emphasized. This differs from the German model, where citizens can write living wills even without preventive medical information (article 1901a BGB).

The Italian Bill limits the validity of ADs to written documents[180], which will be an integral part of the patient's medical record[181]. This is in contrast

[180] All the proposals – except proposal 13 – have established the same principle. In specific this mistake has been codified in: proposal 5 (article 1, section 1); proposal 443 (article 1, section 1); proposal 1142 (article 2, section 1); proposal 1298 (article 3, section 1); proposal 1432 (article 1, section 1, let. f)); proposal 2229 (article 3, section 4); and proposal 2264 (article 2, section 1). Instead, proposal 13 (article 18) has adopted the phrase "personal declaration" without limiting them in written declarations. In addition, the proposal 2229 – as the proposal 2350 – recognizes the need that physician must sign the document; the proposal 443 states that ADs can be written only in front of a Noter and a physician (article 13, section 1); the proposal 1298 emphasizes the importance of two witnesses (article 3, section 7); the proposal 2264 (article 2, section 2) establishes that these documents must be written in front of the Municipality that the citizen has his/her own residence. The proposal 13 states

with the ethical principle of autonomy, which demands that expressed prior choices of the patient should be respected whether they are stated verbally or in writing, in an official legal document or informally.

The Italian Parliament did not follow the French or German models, where ADs, under certain conditions, are valid also in oral form. In France, oral advance directives are valid in two cases (article 1111-17 CSP). The first case – which takes into consideration people who are incapable to write – is when the oral statement is transcribed by two witnesses, who must sign it. The second case is that of an oral medical declaration given to the doctor in charge, who must record it into the patient's case history. It should be noted that within all the new proposals, only proposal 13 has adopted the same policy (article 23, section 1, let. d)).

However, in Germany, oral declarations are legally binding: they are considered as treatment wishes (*Behandlungswünsche*) in the case of a specific oral declaration that matches the patient's actual medical situation, or as a presumed wish (*mutmaßlicher Wille*) in case of general statements (article 1901b, section 2 BGB) (e.g., see Sect. 2.5.1.).

that oral declarations received by the physician or clearly documented through video registration are valid (article 23, section 1, let. d)).

[181] All the proposals – except proposal 443 and 1432 – have established the same principle. In specific this mistake has been codified in: proposal 5 (article 3, section 2); proposal 13 (article 16, section 1); proposal 1142 (article 4, section 2); proposal 1298 (article 3, section 2); proposal 2229 (article 4, section 5); and proposal 2264 (article 2, section 3).

The insistence on written form is exceptional in the Italian legal system because, as recognized from jurisprudence (C. Cass. 27 January 2010, no. 1713; C. Cass. 1 April 2008, no. 8449; C. Cass. 2 May 2007, no. 10121), the legal system is based on liberty of forms. It should be noted that this expectation has been justified in three main ways.

First of all, the law that introduced the notion of support guardian (*amministratore di sostegno* – Law no. 6 of 9 January 2004)[182] requires a written and notarized document in the case of personal designation[183] of a guardian. Since both these legal institutes (surrogate and support guardian) are legal proxies who have the power to decide in case of patient's unconsciousness, it derives that also in case of nomination of a surrogate, the written form is demanded. Moreover, the written form requires a higher evaluation compared to oral declarations, it gives more legal certainty, and it avoids trials to establish the patient's wishes. Furthermore, ADs are considered as unilateral acts that produce a legal effect in the non-pecuniary

[182] The interpretation of this law by the Italian jurisprudence will be examined in the next chapter of this thesis.

[183] There is a difference between designation and nomination of the support guardian. Italian jurisprudence agrees unanimously that Italian citizens have the right to designate their care guardian within the formalities established in article 408 C.C. But, according to the current position of the Court of Cassation, citizens do not have the right to nominate their guardian when they are still fully competent (20 December 2012, no. 23707) (e.g., see Sect. 3.4.).

sphere and the Italian system has always established to them the writing *ad substantiam* – the contract must be in a written form; otherwise is invalid[184].

In article 4, section 2 the Chamber of Deputies has added, compared to the first draft approved by the Senate in 2009, that any statements of intent or desire expressed by the individual not conforming to the forms and usages established by this law have no value and cannot be used in order to reconstruct patients' wishes. This has been considered as a political reaction to the case-law of Englaro.

The Italian choice contrasts with the French and German models, where agents can modify or revoke their decision at any time without special formalities. Specifically, in France, the modification or revocation of advance directives can be made even by simple unequivocal behaviors (article 1111-18 CSP). Similarly, the German law of 29 July 2009 states that ADs can be modified and revoked "*informally at any time*"[185] (article 1901a, section 1 BGB).

[184] Examples of this principle are the recognition of a natural child (article 254 CC), its legitimacy (article 285 Civil Code), and the choice of guardian (article 348 CC).

[185] The revocation of a written living will "at any time without formalities" has always been recognized for competent patients. However, it should be noted that the German legal system is influenced by the Hegelian concept of "natural will" which means that any expression of will on the part of a person who is not fully legally competent should be taken into consideration. Furthermore, the Law of 18 February 2013 (*Gesetz zur Regelung der betreuungsrechtlichen Einwilligung in eine ärztliche Zwangsmaßnahme*) modifies article 1906 BGB by valuing "natural will" even in the case of end-of-life decision-making. According to this article, even if the patient is not

As in Austria (article 7, section 1, law of 8 May 2006)[186], in Portugal (article 7, section 1 law of 16 July 2012), and in the old version of the French law (article 1111-11 CSP)[187], the Italian Bill limits the validity of ADs. The Italian legislator extends it to 5 years. The policy has been justified with the opportunity to have make "living wills" as unambiguous as possible. As it was emphasized by the NBC (2003, p. 6), the ambiguity of ADs is a result of a *"the*

legally fully competent, he can still give his/her opinion regarding medical treatments by opposing forced treatment agreed between a guardian (or surrogate) and physician in charge of the patient; however, this article does not state how an incompetent patient's opinion can be taken into account when his/her surrogate and physicians agree to withhold treatment. Thus, due the fact that the Law of 18 February 2013 codifies the Hegelian principle of "natural will" in ADs, the phrase "at any time without formalities" could be interpreted in a broader way – probably through a non-*originalistic* interpretation – by giving to citizens who are not fully legally competent (e.g., patient with dementia who remain alert, involved in their situation and able to interact with their environment; but especially in cases of a patient with severe dementia where the patient's competency is in serious doubt) the possibility to change their written living wills through oral declarations. However, these declarations should be clear and repeated continuously by the incompetent patient, and judges should have good reason (such as patient's benefit or wellbeing and/or advance in medical discoveries) to disagree with the guardian (or surrogate) agreement with their physician and the patient's written living will.

[186] In Austria ADs could be legally-binding or not. In case of legally binding AD, the interested party must receive complete medical information by the physician and legal information by the Noter. In addition, this document is valid for five years; if not renew with the same formalities, it will have only an advisory power. This document may be registered in the Austrian Chamber of Nataries.

[187]The old version of the French law established that advance directives have a validity of 3 years. Nevertheless, they could be renewed by a simple signature of the existing document (article 1111-18 *Code de la Santé Publique*). On the contrary, the new version of the French Law of 2015 does not establish any time-limited of these documents.

distance, psychological and temporal, from the condition that AD has been written to the concrete medical condition that it should be executed." This decision is in harmony with the idea of some scholars who consider the renewal of ADs to be crucial. According to them, for a patient who has undergone a cure, this review should occur every 1–5 years (Erin and Harris 1994). In addition, the periodic renewal of directives make it possible to keep up with the situation encountered. The Italian bill requires the renewed document to be completed with the same formalities as the original. This policy has been repeated identically in the new proposal 2229 of March 2014.

It seems that the Italian Legislator has adopted the philosophy of Derek Parfit (1994), who believes that personal identity is not continuous over time and place. This is in contrast with the Dworkin's theory (1986), which rejects the idea of loss of personal identity; his theory has been adopted in other European countries that do not limit the validity of ADs in time.

To avoid problems that could arise from the long time that can pass between the formulation of ADs and their execution, two suggestions could be made. The first comes directly from the interpretation of paragraph 62 of the Explanatory Report on the Convention on Human Rights and Biomedicine of April 1997[188]; according to it, ADs are valid until the moment there is a

[188] The same policy has been repeated in the Explanatory Report on the Recommendation CM/Rec (2009) 11 of the Council of Europe (par. 180). In addition this has been applied in England and Wales (article 25, section 4 let c)) and in

medical discovery or a change in the patient's pathology that if the patient had known them, would have changed his or her medical instructions[189]. The second solution comes from the German model, where Parliament has resolved the uncertainty of personality changes entailed by the absence of this temporal limitation by giving broader powers to the surrogate (article 1901a, section 1 BGB), who must verify whether instructions given in a living will adequately address the actual medical situation. It seems that this policy has been also implemented by the new French policy of March 2015 in article 1111-6, section 2 CSP.

Article 4, section 6 states that in case of urgency or when the risk of death exists, ADs are not applicable. No other Western European legislation has so limited personal autonomy. This section is not only in contrast with articles 3, 13 and section 2 of article 32 of the Italian Constitution (see above), but also limits the application of this law in cases of patients with terminal illness to the period before they face the risk of death. This section makes an unethical distinction between adults lacking capacity and other patients. Furthermore, the legal reason that ADs written with all the formalities established in this bill are not valid in case of emergency is not understood.

Austria (article 10, section 1, nr. 1 of 8 May 2006, *Patientenverfügungs-Gesetz – PatVG*),

[189] This seems to be the policy adopted by the majority of the proposals 13 (article 21, section 1), 1432 (article 1, section 1, let. h)), 1298 (article 3, section 2), and 2264 (article 2, section 4).

Therefore, some scholars have considered this Bill 'useless' (Neri 2010) or 'poorly reasoned' (Guarnieri 2009) because the Italian Code of Medical Ethics prohibits futile treatment, and this bill states that ANH cannot be the object of ADs and that ADs cannot be applied when a patient's life is at risk. Hence, it makes no sense to legislate on ADs because there is so little scope to apply them to concrete medical situations.

In conclusion, the Italian Parliament should not establish such a rigid form of ADs. Oral medical declarations made under certain circumstances could be considered valid. Furthermore, ADs should not be time-limited: problems derived from the long time that could pass between their formulation and the time they carry out could be resolved by taking into consideration the model established by the Explanatory Report of the Convention of Oviedo or by giving an extensive power to the surrogate.

In addition to an ad hoc law ruling ADs, the Italian medical community should establish clear guidelines in line with this law. In the international debate, the most recent guidelines are the "Care of the Dying Adult" in UK, which will be published in December 2015. The draft of it, published at the end of July 2015, is composed of 67 points. This document has applied a clear normative approach and has been well-accepted by the medical and legal communities. The aim of it is to modify the Liverpool Care Pathway. These guidelines have underlined the interdisciplinary approach in end-of-life and the communication between the medical staff, the patient, and the patient's family and relatives.

4. The appointment of a surrogate in Italy: legal comparison with the Mental Capacity Act of 2005

In accordance with article 6 of the European Convention on Human Rights and Biomedicine and principle 4 of Recommendation CM/Rec (2009) 11 of the

Council of Europe, article 6 of Italian bill no. 2350 recognizes the possibility for a fully competent person to nominate a surrogate. The nomination of a surrogate highlights the relational approach of autonomy (e.g., see Sect. 1.2.). While the individualist model will consider as non-autonomous the person who relies on the opinions of others, with the relational model it is not unreasonable for a patient to defer his or her decision to another person. With the new model of autonomy, the role of the legal proxy – especially that of the surrogate – is accentuated.

This is not the first time that the Italian Parliament has recognized the importance of legal proxies for not fully competent patients.[190] Before the Bill 2350, the NBC (2003) had underlined the importance of the surrogate, being the subject nominated by the patient who has the duty to communicate with the medical staff. In addition, this possibility has been confirmed in all eight other proposals made during the new parliament.[191] The importance of this provision lies in the fact that it creates an exception to the general rule – also common in the other Romance speaking countries[192] and in England before

[190] According to article 4 of Legislative Decree no. 211 of 24 June 2003, clinical experiments on incompetent adults can be carried out only with the consent of the legal proxy, who must base it on the presumed wishes of the incompetent adult. Furthermore, article 13 of law 194 of 22 May 1978 states that a request for abortion can be made not only by a disabled woman, but even by her legal proxy.

[191] It should be noted that in the proposal no. 443 the nomination of a surrogate is presumed.

[192] In France: article 2003 Civil Code; in Portugal: article 298 Civil Code; and in Spain: article 1732 Civil Code

2005[193] – that power of attorney is valid only while the donor is fully competent.[194]

However, unlike the MCA,[195] which uses the change established by principle 4, section 2 of Recommendation CM/Rec (2009) 11, [196] neither Italian bill no. 2350 nor the other eight new proposal-bills regarding end-of-life decision-making offers the chance to nominate more than one surrogate. This could create difficulties when the only surrogate cannot be contacted.[197]

[193] Article 1 of the Enduring Powers of Attorney Act of 26 June 1985

[194] The general rule of invalidity of power of attorney in case of the donor's unconsciousness comes from the combination of article 1389 and article 1722, section 1 no. 4 of C.C.

[195] Article 10, section 4 of the Mental Capacity Act of 2005. The maximum number of lasting power of attorney is 5 (article 6 The Lasting Powers of Attorney, Enduring Powers of Attorney and Public Guardian Regulations).

[196] Principle 4, section 2 of the Recommendation CM/Rec (2009) 11 of the Committee of Ministers to member states on principles concerning continuing powers of attorney and advance directives for incapacity (Adopted by the Committee of Ministers on 9 December 2009 at the 1073rd meeting of the Ministers' Deputies). It should be noted that England is the only country within Romance-, English- and German- speaking countries, that has explicitly applied this possibility.

[197] This is why during the parliamentary discussion regarding the Mental Capacity Act, the Joint Committee decided to give the opportunity to the donor to nominate more than one surrogate. This Committee has also allowed the judge to nominate more than one deputy in case of total absence of the surrogate (Joint Committee on the Draft Mental Incapacity Bill 2003).

Moreover, two or more surrogates may be the solution to undue concentration of power, or to reduce the risk of family dispute.[198]

Article 6 of bill 2350 requires that an AD giving lasting power of attorney for health care affairs must be in writing and the surrogate must sign it. This formality – which copies the English model – has been confirmed in the draft bill no. 2229 (article 6, section 1). But, while in Italy, the surrogate must sign the AD to accepting the role of attorney for health care affairs, whereas in England, the donee must sign it only in case that the donor wants to refuse life-sustaining treatment.[199] The signature in the 'surrogate will' by the surrogate will create uncertainty regarding the nature of this document since its qualification as a unilateral act or as a contract will become more difficult to determine. This qualification is importance because the infringement of a contract has stronger legal consequences than the breach of a unilateral act.

[198] Council of Europe, Explanatory report Recommendation CM/Rec (2009) 11, par. 98.

[199] In England, ADs that refuse medical treatment must be written (section 5.45 of the Mental Capacity Act Code of Practice). But, in case of withdrawing life-prolonging treatment, the living will must be in written form and signed by the donor in the presence of a witness who also signs it, or acknowledges the signature, in the donor's presence (article 25, section 5 and 6 Mental Capacity Act). Further, in the case of withdrawing artificial nutrition and hydration from a patient in persistent vegetative state (PVG) – a patient who is in a vegetative state for more than 6 months – or in a condition similar to PVG, a declaration from the Court must be sought (Airedale NHS *Trust* v. *Brand* [1993] AC 789).

Article 6, sections 5 and 6 state that, if nominated, the surrogate must ensure that the patient is not given futile medical treatment[200] or subjected to therapeutic abandonment. This is a reinforcement of the principle established in article 16 of the new Italian Code of Medical Ethics.[201] This policy is a result long bioethical discussion regarding the patient-proxy relationship. The core of this relationship is trust, which means giving to the surrogate the power to decide with some exercise of discretion (Baier 1995). Although citizens are aware of its risks (Lagerspetz 1997), they still choose to trust because trust is an elementary human value (Baier 1993). With the aim to resolve problems regarding the interpretation of patient's preferences and values,[202] several scholars have suggested that State laws are liable to check proxies' activities or to address them some obligations (Kapp 1999, and Sabatino 1999). This is an important policy since citizens do not have control over surrogates' activities.

[200] It should be noted that, contrary to article 1, section 1, letter F, in article 6, the Italian parliament does not use the concept of 'extraordinary treatment', which has religious connotations, and has been increasingly rejected as irrelevant to decisions about life support, at least in secular contexts outside of its origins in Roman Catholicism (Brock 2009).

[201] Article 16 of the Italian Code of Medical Ethics prohibits directly any kind of medical futility. Therapeutic abandonment is not directly mentioned, but inferred from an interpretation of article 3 – which establishes the general principle that should guide medical practice.

[202] Deciding for others has been considered as a 'psychological fiction' which depends on different perceptions and relationships (Tia 1999).

Further, the surrogate must ensure that crimes such as homicide (article 575 Penal Code – P.C.), homicide by request of the victim (article 579 P.C.) or aiding or inciting suicide (article 580 P.C.) are not committed.[203] All these norms are confirmed in proposal no. 2229 of 26 March 2014 (article 6, sections 5 and 6). However, no civil or criminal liability is specified for surrogates who overlook these duties; the general norms of the civil and penal code must therefore be used. According to article 333 Code of Criminal Procedure (C.C.P.), citizens are not obliged to report crimes established in article 575, 579 or 580 P.C.[204] However, according to article 331 C.C.P., medical staff are obliged to report them.

According to article 25 of the Italian constitution and article 1 P.C. – which establish the principle of n*ullum crimen, nulla pœna sine prævia lege pœnali* – in these cases the surrogate does not have any criminal liability in these cases. If this bill were to become law, the problem for Italian jurisprudence to resolve is whether the surrogate should be liable for civil damages. Although most of the Italian bioethical community consider ADs unilateral act (Canestrari 2003), since article 6, section 1 establishes the need for the surrogate's signature and article 6, section 6 requires particular

[203] It should be noted that, contrary to article 1, section 1, letter C, in article 6 the phrase 'any kind of euthanasia' – which might be ambiguous – does not appear.

[204] Article 333 Code of penal procedure establishes mandatory reporting for citizens in cases of crimes against the State (article 364 P.C.) and in case of buying or receiving money or things which derive from other crimes (article 709 P.C.).

diligence from the surrogate regarding the protection of the patient's health care interests, some judges might make surrogates liable for civil damages in these cases. This will increase doubts in this area, which will lead to the infringement of the principle of legal certainty. As it is known, Italy is not part of the common law legal systems. It follows that the principle of precedence – i.e. that the rule established in a previous legal case is either binding on or persuasive for a court or other tribunal – is not applied.

4.1. The cases of absence of a surrogate

Article 6, section 8 of bill no. 2350 pays particular attention to surrogate absence by highlighting the importance of patient's family.[205] This policy has

[205] The value of the family is affirmed in six of the eight new proposals. In chronological order: 1) the proposal no. 5 of 15 March 2013 establishes this order: spouse, established partner, children, parents, relatives till the fourth grade (article 4). In case of their absence, the decision should be taken form the ethical committee of the hospital or if there is none, by the primary care trust (*azienda sanitaria locale*) (article 8); 2) proposal no. 13 of 15 March 2013 states that physicians should speak with a patient's relatives (article 9, section 3). In case of their absence, article 406, section 3 C.C. should be applied; therefore, a decision must be sought from the Court of Guardianship (article 9, section 3). 3) Proposal no. 443 of 10 April 2013 establishes this order: spouse, children, established partner, established parents and relatives up to the fourth degree (article 3, section 2). In case of their absence the decision should be taken by the Court of Guardianship (article 3, section 2); 4) Proposal no. 1142 of 4 June 2013 establishes the same order of the proposal no. 5 of 15 March 2013 (article 5); 5) Proposal no. 2229 establishes the same order as bill no. 2350 (article 6, section 8); 6) the proposal no. 2264 this order: spouse, stable

also been adopted in other Romance speaking countries[206] and in Switzerland.[207] An automatic proxy scheme would be more congruent with the sense of fairness in society (Sahm 2005). In addition, this policy is more in accordance with the principles of subsidiarity and respect for private and family life, which should be considered as a pivotal state interest (Jox et al. 2008). Furthermore, most ethicists and politicians prefer family surrogates (Kim et al. 2009), as the most practical and cost-effective surrogates (Probst

partner, children, parents, relatives till the fourth grade (article 2). In case of conflicts the Court of Guardianship will be sought. Unfortunately, in proposals 5, 443 and 1142, which establish a precise order, there is a lack of procedural norms in case of conflict between children.

[206] In France: article 1111-6 CSP suggest that a surrogate could be a parent, a relative. In addition, in case of absent of a surrogate a fixed order has been established in article 1111-13 CSP that establishes this order surrogate, family, living wills. In Portugal, article 11 states that employees of the National Register or Heath Care system could not be nominated as a surrogate, expect they have a family relationship with the patient (*Regula as diretivas antecipadas de vontade, designadamente sob a forma de testamento vital, e a nomeação de procurador de cuidados de saúde e cria o Registo Nacional do Testamento Vital,* law of 16 July 2012); and in Spain: article 9 states that if the patient is incapable and there is an absent of a legal representative – even a surrogate – informed consent with be granted by virtue of relationship or de facto reasons (*Básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica,* law of 14 November 2002)

[207] In Switzerland, in case of absence of a surrogate, article 378 ZGB establishes this order: surrogate, person nominated in 'der Vorsorgeauftrag' ('Precautionary Mandate'); guardian; spouse or registered partner; person living in the same household if he regularly assist the incapable person; children if they regularly assist the incapable person; parents if they regularly assist the incapable person; or brothers and sisters if they regularly assist the incapable person.

and Knittel 2001). Moreover, generally family members are nominated as patient's legal proxy (Budroni 2014, and Cohen-Mansfield et al. 1991)[208] and most end-of-life decisions are made by family members (Karasz 2010). Recently, the Irish Supreme Court has underlined the aspects of family solidarity (*North Western Health Board v. W (H)* [2001] IESC 70). Further, this approach highlights the concept of 'relational autonomy', which considers the person as part of a society.

Unfortunately, this approach has some disadvantages. Firstly, the traditional family is no longer common in Western Europe, owing to the high rate of divorce (ISTAT 2014). Several studies have shown that family dynamics strongly influence end-of-life decisions (Broom and Kirby 2013, Hudson and Payne 2011, Goldberg 2010, and Grande et al. 2009). This influence depends on the role that the patient and the surrogate have in the family (King 2006 and Aoun 2005). In addition, 'family-centred care' largely remains an ideal rather than a grassroots reality (Broom and Kirby 2013, Hudson and Payne 2011 and Grande et al. 2009). Secondly, this could lead to an opt-out system, where citizens do not nominate a family member that they consider not to be in line with their personality (Jox et al. 2008). Thirdly, since the law would already have pre-established an order of proxies for medical decision-making, citizens would lose the incentive to write ADs.

[208] For instance, in Germany, in 2009, 62% of the guardianships were given to persons inside the patient's family (Bundesministerium der Justiz 2009). On the contrary: Ginger et al. 2006.

The Italian legislator could follow the model established in the MCA, where when there is no living will, no surrogate has been appointed and the Court of Protection has not appointed a deputy, treatment may be provided to an adult lacking capacity only if that treatment is in the patient's best interests.[209] This model is quicker and avoids courts judgements in case of disagreeing family members in the same degree of kinship (Probst and Knittel 2001).

In the Italian Bill, the absence of an impartial authority to resolve disagreement between surrogate and physicians and to control his or her activity has been noted. Regarding the first problem, the previous draft of 2009 in its article 7, section 3 established an internal medical committee to resolve these conflicts, although their decision would not have been legally binding on physicians.

In case of conflict between surrogate and doctors two different solutions could be used. The first is to resolve the conflicts within the hospital; the second is to resort to a 'specialized' judge. The first approach provides a quicker decision based on medical criteria, and has been implemented in

[209] Contrary to the Italian concept of a patient's 'best interest', in England, this concept is broader than medical interests and includes the patient's own wishes and values (British Medical Association 2007). Moreover, Part 1, principle 4 Mental Capacity Act of 2005 states that physicians must "*so far as reasonably practicable, permit and encourage the person* [even without full capacity] *to participate, or to improve his ability to participate, as fully as possible in any act done for him and any decision affecting him*". Additionally, they must considered patient's *"past and present wishes*".

Portugal in cases of medical objection (article 9 Portuguese law no. 25 of 16 July 2012) in addition to having been proposed by SIAARTI in its document of 2006; the second model is more impartial, and has been implemented in Great Britain and in Germany.[210]

Since article 24 of the Italian Constitution has recognized the right to justice, it follows that in case of conflict between surrogate and doctors a judge's ruling should be sought. As this law does not establish a 'specialized' judge to decide in these cases, a judge from the ordinary jurisdiction would take the decision. This will arise two main issues. Firstly, in end-of-life decisions where ethical, legal and medical principles are involved, the need for 'specialized' judge is fundamental. Secondly, in end-of-life situations the decision by a judge needs to be made expeditiously, and the ordinary jurisdiction – even in cases of summary procedures introduced by the law 69 of 19 June 2009 – is too overburdened to do so.

Moreover, the absence of an authority to oversee the surrogate's activity should also be addressed. The Italian legislator could consider the model established in the MCA of 2005, where article 23 establishes that the Court of Protection must control the surrogate's activity. Only a judge can oversee the surrogate's activity, being impartial regarding the conflict

[210] In England and Wales: articles 45-53 MCA of 7 April 2005; in Ireland: articles 13-32 of the Assisted Decision-Making (Capacity) Bill 2013; In Scotland: article 50 of the Adults with Incapacity (Scotland) Act of 29 March 2000. In Germany: article 1904 BGB

between the surrogate and the physician in charge, and the decision must be taken according to the patient's right to self-determination rather than medical criteria.

The establishment of an authority to resolve disagreement between surrogate and physicians and to oversee the surrogate's activity is important for three main reasons. Firstly, some empirical studies have shown that some surrogates – due to clinically diagnosed conditions, such as stress, depression, and anxiety – could themselves lose their mental capacity (Siegel 2005). Secondly, sometimes some surrogates might have dubious motives in that they are looking out for their own interests rather than the patient's interests (Pope 2012). Thirdly, since the surrogate must sign his nomination and particular diligence has been required by him the principle of legal coherence imposes that an impartial organ should resolve disagreement between surrogate and physicians and to oversee the his activity.

5. The application of the Italian law no. 6 of 9th January 2004 in Italian Jurisprudence: the appointment of a support guardian for health care decisions

Although Italy has no law on ADs, Italian jurisprudence has protected the right to nominate a legal proxy for health care affairs in cases of future

unconsciousness through the interpretation of law no. 6 of 9 January 2004[211] which introduced to Italian law the role of support guardian (*amministratore di sostegno*) in articles 404-413 C.C. The protection by the Italian jurisprudence is required since the withdrawal of treatments from unconscious patients is common in medical practice (e.g. see Sect. 3.1.). Moreover, studies have shown that Italian citizens – like the other western European citizens – prioritize quality of life rather than extension of life (Higginson et al. 2014). Although national legislators have applied different policies (e.g. see Chap. 2), studies based on citizens' preferences demonstrate that only a small minority (6% of the interviewees) prioritizes extending life rather than quality of life (57% of the interviewees).

The intervention of the 2004 parliament aimed to avoid the broader application of the legal discipline of interdict (*interdetto*) and of inability (*inabilitato*) (Vimercati 2011). The most recently-introduced role of support guardian must be distinguished from the others according to its function of giving concrete assistance, rather than according to the ward's degree of incapacity (C. Cass. 25 October 2012, no. 18320; 26 October 2011, no. 22332; and 12 June 2006, no. 13584).

This law has been a direct application of article 13 (right to personal liberty) and article 32 (right to health) of the Italian Constitution. The

[211] This law introduces to Italian law the concept of the incompetent person who is seen as needing personalized and flexible protection, including protection of human dignity, not merely administration of the person's estate.

combination of them has led to the protection of the right to self-determination in health care. These rights are correlated together; however, the right to self-determination differs from the right to health, due to the fact that it is broader and involves patient autonomy (C. Cost. 15 December 2008, no. 438). The right to self-determination is not limited, because in the Italian legal system no law imposes a duty to live (e.g. see Sect. 3.1.). In addition, this law applies the rules established in the Convention on the Rights of Persons with Disabilities of 13 December 2006, ratified in Italy by law no. 18 of 3 March 2009. As in all the other Romance speaking countries, in case of nomination by a judge of a legal proxy, the Italian legislator has adopted a 'pluralistic' model, which is in contrast with the 'monistic' model adopted in Germany and in Austria.

The main characteristic of this non-traditional institute is the promotion of the patient's personality.[212] The legal status given to the person who has a support guardian is less invasive (C. Cost. 9 December 2005, n. 440) than the status of interdict or inability[213] because with a support guardian the ward does not lose the legal competency to act. Furthermore, the role of the support guardian is general and elastic, whereas the traditional two statuses

[212] This result comes from the interpretation of article 405, section 4 together with article 408, section 1 and article 44 of the Execution Dispositions of C.C.

[213] It should be noted that the status of interdict bars the person from acts of extraordinary administration, whereas the status of inability bars the person even from ordinary administrative acts.

are rigid and specific. The duties of the guardian depend on a judge's ruling, based on the patient's physical and psychological health (C. Cass. 22 April 2009, no. 9628).

The application of articles 404-413 has entailed three main problems. 1) Can the guardian oversee the ward's health? 2) If yes, what legal standard should the guardian use when making decisions about the patient's health care issues? 3) Does the close similarity between the guardian for health care issues and the surrogate entail the legal recognition in Italy of ADs giving lasting power of attorney for health care affairs?

The first question that Italian jurisprudence had to resolve regarding the application of the role of support guardian was whether it had standing to oversee the ward's health care issues. The question is raised by a literal interpretation of article 411, section 1, which does not mention article 357 C.C. However, the combination of article 404, section 1 with article 405, section 5 and with article 44 of the implementation disposition of C.C. entails that the support guardian has the attorney for health care decisions (Gorgoni 2012). Furthermore, since the support guardian protects the rights of the ward within the activities established by the judge's ruling, only this interpretation effectively safeguards the rights of people with disabilities, recognized by the Convention on the Rights of Persons with Disabilities. They are fully competent, but in that particular moment they are clinically unconscious or lack capacity to take care of their health.

The second question regards the standard that guardians should apply to wards' health care decisions. The guardian, as the surrogate, acts 'for' the ward (C. Cass. 16 October 2007, n. 21748).[214] The lines of responsibility run only from the support guardian to the court or from the guardian to the ward without a reciprocal obligation towards the guardian. The support guardian must not be considered equal as an agent (Frolik 2007-2008). If the agent under a contract of agency must consider the behavior of a reasonable person, the support guardian must consider the personal value and preferences of *that* person by considering the narrative approach of his identity. Thus, when making health decision, guardians are expected to follow the substituted judgment doctrine (C. Cass. 20 December 2012, no. 23707; Trib. Rome 10 March 2009; Trib. Modena 23 December 2008; Trib. Trieste 17 December 2008; and C. Cass. 16 October 2007, n. 21748).

The third question relates to the juridical debate over whether Italian citizens have the right to nominate – and not only designate – their support guardian when they are still fully competent and therefore support guardian and surrogate are considered identical. The answer depends on the interpretation of article 408 C.C. – which allows citizens the right to designate a guardian – and on the meaning given to the pre-condition requirement of

[214] This ruling was considered correct by the Italian Constitutional Court (C. Cost. Ordinance of 8 October 2008, no. 334). The High Court of Cassation stated that a guardian can act as legal proxy to give medical consent on behalf of the patient, as well as the tutor (in case of interdict). Furthermore, this decision introduced the notion of substitution of judgment to the Italian legal system.

actual incapacity – which Italian jurisprudence has added to the legal role of support guardian. [215]

Before discussing this problem, a premise must be mentioned. In accordance with the formalities of article 408 C.C., Italian citizens can designate – through the so-called guardian will – a guardian to look after their health affairs.[216] The instructions given in the 'guardian will' are legally binding only between citizens (Frolik 2007-2008). The judges must take them into account; they can only dismiss a designated guardian with serious reason.[217] The instructions given by the citizen are binding on the guardian, but not on the judge (C. Cass. 22 April 2009, no. 9628), because the aim is for the judge to retain discretion (Bonilini 2007).

Italian jurisprudence and doctrine is divided on whether citizens have the right to nominate their guardian when they are fully competent. According to a part of Italian Jurisprudence (Trib. Verona 4 January 2011; Trib. Cagliari

[215] For Italian jurisprudence, the two absolute conditions for the nomination of the support guardian – according to interpretation of article 404, section 1 of C.C. – are: the patient's state of incapacity (subjective requirement) and the inability to take care of his/her own health (objective requirement).

[216] However, the ruling of the Tribunal of Modena of 13 May 2008 states that even absent these formalities, the individual right to designate a guardian, accompanied by certain other evidence, prevails over the rigid formalities established by article 408 C.C. (although these aim to protect the certainty of a person's wishes, they only work in an ideal world in which everyone writes their wishes with a lawyer's help).

[217] 'Serious reason' means modification of the pathological situation compared to what the want had been imagined that justified a change of his wishes (Salvatore 2013).

14 December 2009; Trib. Florence 8 April 2009; Trib. Rome 3 April 2009; Trib. Pistoia 8 June 2009; and C. Appeal Florence 3 July 2009, no. 361 and 365), to the current position of the Court of Cassation (C. Cass. 20 December 2012, no. 23707),[218] and to part of Italian Doctrine (Balestra 2011, and Busnelli 2011), citizens do not have the right to nominate – which is different from the right to designate – their guardian when they are still full competent. This interpretation, which is an *originalist*[219] interpretation, is a direct result of a procedural interpretation of the law (C. Cass. 20 December 2012, no. 23707). According to this, the instructions contained in the 'guardian will' are legally binding only between citizens, and not on the judge.

The rationale of the institution of support guardians is to give effective care according to a specific clinical and medical prognostic, because this is an

[218] Court of Cassation (section I civil), decision of 20 December 2012, no. 23707 is the first and the only ruling from the Italian High Court of Cassation about the legal discussion if a competent citizen could nominate in advance a guardian for his/her future eventual unconsciousness. This decision conforms the decision of the Tribunal of Trento, ruling of 29 November 2010 and that of the Court of Appeal of Trento, ruling of 19 April 2011, no. 862.

[219] *Originalist* theories attempt to link interpretation to the time when the law was enacted. This style of interpretation brings certainty into law. Within *originalist* theories there are two different groups: *textualism*, which focuses on the meaning of words, and *intentionalism*, which emphasis the drafting history of the bill. The first group would say that the Italian parliament did not intend to rule on ADs because: 1) in article 404 C.C. the verb 'to be' is in the present tense, not the future; 2) article 405, section 1 states that the judge's decree takes immediate effect; 3) article 408, section 1 uses the verb 'to designate' and not 'to nominate'. The second group would say that the Italian Legislator did not intend to legislate on ADs because a different bill governing ADs was being discussed in 2009 and 2011.

act *rebus sic stantibus* (Corda 2010). A judge's decision is necessary to verify the patient's state of incapacity, their inability to look after their own health and the suitability of the guardian to be nominated (Buffone 2013). Moreover, only this legal reasoning avoids difficulties in defining the time of several legal publications.[220]

On the other hand, some court decisions (Trib. Grosseto 16 May 2012; Trib. Treviso 7 June 2011; Trib. Florence 22 December 2010; Trib. Modena 14 May 2009; Trib. Prato, 8 April 2009; Trib. Modena 23 December 2008; Trib. Modena 5 November 2008; Trib Bologna 4 June 2008; Trib Modena 13 May 2008; and Trib. Parma 2 April 2004) and some scholars (Gorgoni 2012, Infantino 2011, D'Avack 2009, Pasquino 2009, Rodotà 2009, and Sesta 2008) have recognized the possibility for fully competent citizens to ask a judge to nominate a guardian. According to them, incapacity is needed for the production of legal effects and not for the guardian's nomination. This legal reasoning is based on the interpretation of the phrase 'even if' in article 406 C.C.[221] According to them, although this might be a forced interpretation of the

[220] Legal documentation that must be completed for the nomination of a guardian includes: the registration of the degree in the Court Record (article 3, section 1, letter b, Decree of President of Republic No. 313 of 14 November 2002); the addition to the Register for guardians (article 405, section 6 Code of Civil Procedure and article 49 *bis* Disposition of application of C.C.) and communication to the Office of Civil Status (article 405, section 7, Code of Civil Procedure).

[221] Article 406 C.C. states that citizens without full legal capacity can ask a judge to nominate a support guardian. The use of the world 'even if' suggests that a person with full legal capacity could ask for a guardian.

textual interpretation, it is the only interpretation that fully protects the constitutional right to self-determination.

The nomination of a surrogate when the person is still competent would avoid problems when physicians need to make a quick decision and Courts – even in cases of summary judgment – take a long time to decide. Further, this *non-originalist* interpretation[222] is connected with the idea that courts should protect fundamental rights, even when doing so goes against the will of the legislature, because rights are inherently anti-majoritarian (Letsas 2010).

A judge who has to interpret the law on support guardian should take into consideration two contrasting principles. On one hand, the magistrate should protect the right to self-determination in health care, which comes as an interpretation of article 13 and 32 of the Italian constitution. On the other, the judge should take into consideration the literal and teleological interpretation of articles 404–413 C.C.: with law no. 6 of 9 January 2004, the Italian parliament did not intend to legislate on ADs giving lasting power of

[222] The *non-originalist* interpretation means that these are rights which are not expressly mentioned in the text but which it is proposed should nevertheless be 'read into' it. According to them, the protection of the right to self-determination should be not theoretical and illusory: thus, if the Italian parliament failed to legislate on ADs in 2009 and 2011, law no. 6 of 9 January 2004 must be applied to fulfill this gap and to protect the human right to self-determination. This kind of approach is the same as that of the European Court of Human Rights, which inaugurated it in the famous case Golder v. United Kingdom (Letsas 2010).

attorney for health care affairs. The roles of surrogate and support guardian are similar but not equal.[223]

However, with the aim to give actual legal protection when at present there is no *ad hoc* law regarding 'surrogate wills', a guardian can be nominated – even if the citizen is fully competent – only in cases of future programmed medical treatment that entails unconsciousness (Trib. Trieste 3 July 2009; Trib. Parma 2 April 2004; and Trib. Rome 19 March 2004), or in cases of Jehovah's Witnesses for blood transfusion (Trib. Bologna 4 June 2008; Trib. Rome 21 December 2005; and Trib. Vibo Valentia 30 November 2005), or for an illness that progressively incapacitates the patient (Trib. Modena 16 September 2008). In all these cases, the condition of incapacity is not eventual or hypothetical, but almost definite. This legal reasoning comes from the interpretation of the combination of article 407, section 2 and article 410 C.C. in the light of the principle of informed consent.[224] Additionally, in all these cases, patients have received detailed medical and clinical information about

[223] On the contrary, according to the Court of Appeal of Florence's decision of 22 December 2010, where it is stated that a guardian is the most appropriate legal figure to implement an AD. It should be noted that the surrogate – and not the guardian – is the most appropriate legal figure to implement AD because in a 'guardian will' the instructions given to the guardian are legally binding only for the guardian and not for the judge, who also has the power to dismiss – if there is serious reason – the guardian designated by the citizen (C. Cass. 20 December 2012, no. 23707).

[224] Informed consent has been considered as a constitutional right through the interpretation of articles 13 and 32 of the Italian constitution. (C. Cost. 15 December 2008, no. 438)

the consequences of their disease, which has been considered important from the Italian legislator[225]

Although the this legal reasoning goes beyond a literal interpretation of articles 404–413 C.C., it takes into account the constitutional right to self-determination without confusing the so-called 'guardian will' with the 'surrogate will'.

[225] The Italian legislator has considered fundamental the fact that the declarant has received all the needed medical information before he or she states in advance his medical directives (article 3 and 4 of the bill 2350). In concrete, article 3, section 1 states that 'the declarant … has received complete medical information … expresses his directions'; and article 4, section 1 states that 'the declarant adult after the provision of appropriate and exhaustive medical information' write the AD.

Summary

The Italian situation regarding end-of-life has been examined through the study of the main documents published by the bioethical and medical communities, the main rulings decided by the jurisprudence, and the analysis of the Bill no. 2350 and the new proposal-bills of the new legislature, which started on March 2013.

Italy is one of the few Western European countries that does not have a specific law governing advance directives. The intervention of the Italian legislator has been asked not only by the jurisprudence, but also by the bioethical and medical communities. The bill should take into account rulings of the Italian Constitutional Court and of Italian judges, who up to now have substituted the Italian Legislator by protecting in individual case-law the patient autonomy and the right to self-determination. Moreover, the experience of other Western European countries should be taken into consideration. In addition to an *ad hoc* law ruling ADs, the Italian medical community should establish clear guidelines in line with this law.

Until then, Italian judges should protect the patient's autonomy by applying the current laws without confusing the legal figure of a guardian with that of a surrogate. The legal roles of guardian and surrogate are similar but not identical. Both surrogate and guardian must decide according to the patient's preferences and values. Both are designated by the patient, but as the High Court of Cassation has ruled, only a judge can nominate a guardian when the ward is unconscious.

In the new legislature, the proposals for a new bill regarding advance directives comprise three from the Senate and five from the Chamber of Deputies, which are proposal-bills nos. 5, 13, 443, 1142, 1298, 1432, 2229 and 2264. It should be noted that the proposal-bills 5 and 1142 are similar. Moreover, the proposal-bill 2229 has adopted the same paternalist and conservative approach of the bill 2350. In addition, the proposal-bill 1432 contains only one article: therefore, it lacks several procedural norms and it makes the false presumption that the European Convention of Human Rights

and Biomedicine of April 1997 is executive in Italy. Generally, all the new proposals – except proposal-bill no. 2229 – have adopted a liberal approach by highlighting patient autonomy. Within them, the proposal-bill 13 is the best policy to protect patient right to self-determination because it regulates not only informed consent and advance directives, but also advance care planning.

Concluding, the Italian Parliament should establish clear rules governing end-of-life issues. It should take into account the principle of patient autonomy, the experience of different western European countries, the rulings of the Italian judges, and the opinion of the bioethical and medical communities.

References:

Amato, D. Vincenti. "Il silenzio della legge e il testamento di vita." In *Il testamento biologico: riflessioni di dieci giuristi* edited by Fondazione Veronesi, 177-188. Milano: Giuffré, 2010.

American Dietetic Association. "Ethical and Legal Issues in Nutrition, Hydration, and Feeding." *Journal of the American Dietetic Association* 108, no. 5 (2008): 873–882.

A.S.P.E.N. Board of directors. "Guidelines for the Use of Parenteral end Enteral Nutrition in Adult and Pediatric Patients." *JPEN. Journal of parenteral and enteral nutrition* 26, no. 1 (2002): 1SA-138SA.

Assamblee Nationale, *Mission d'e´valuation de la loi n° 2005-370 du 22 avril 2005 relative aux droits des malades et a` la fin de vie*, n° 1287, vol. 2, 2008.

Aoun, Samar M. and others. "The experience of supporting a dying relative: Reflections of caregivers." *Progress in Palliative Care* 13, no. 6 (2005) 319–325.

Baier, Annette C. *Moral Prejudices: Essays on Ethics.* Cambridge: Harvard University Press, 1995.

Baier, Annette. "Responseto Olli Lagerspetz." In *Commonality and Particularity in Ethics,* edited by Alanen, Lilli and others,118-122. New York: St. Martin's Press, 1997.

Barni, Mauro and others. "Aspetti Medico - Legali e Riflessi Deontologici del Diritto a Morire." *Rivista Italiana di Medicina Legale* 7, no. 3 (1986): 724 – 734.

Balestra, Luigi. "L'autodeterminazione nel «fine vita»" *Rivista Trimestrale di Diritto e Procedura Civile* 65, no. 4 (2011): 1009-1031.

Berger, Jeffrey T. and Deborah Majerovitz. "Stability of Preferences for treatment among Nursing Home Residents." *The Gerontologist* 38, no. 2 (1998): 217–223.

Bertolini Guido and Boffelli Stefano. "Scelte in fine vita: verso un'epidemiologia delle pratiche." In *Scelte sulla vita: l'esperienza di cura nei reparti di Terapia Intensiva* edited by Bertolini, Guido. Milano: Gullini Studio 2007.

Bonilini, Giovanni. "Le norme applicabili all'amministrazione di sostegno." In *L'amministrazione di sostegno* edited by Bonilini, Giovanni and Augusto Ghizzini, 299-301. Padova: Cedam, 2007.

Bonsignore, Alessandro and others. "Le Direttive Anticipate di Trattamento nella Prospettiva del Legislatore ed i riflessi Medico-Legale", *Rivista Italiana di Medicina Legale e del Diritto nel Campo Sanitario* 34, no. 4 (2012): 1479 – 1493.

British Medical Association. *Advanced Statements about Medical Treatment.* London: BMJ Publishing Group, 1995.

British Medical Association. *Withholding and Withdrawing Life-prolonging Medical Treatment Guidance for decision making*. Oxford: Blackwell Publishing, 2007.

Brock, Dan W. "Medical Decisions at the End of Life." In *A Companion to Bioethics*, edited by Kuhse, Helga and Peter Singer, 263-273. Oxford: Wiley-Blackwell, 2009.

Broom, Alex and Emma Kirby "The end of life and the family: hospice patients' views on dying as relational."*Sociology of Health and Illness* 35, no. 4 (2013): 499-513.

Buffone, Giuseppe. "L'istituto dell'amministrazione di sostegno." *Giurisprudenza di Merito* 43, no. 11 (2013): 2376-2382.

Budroni, Helmut. "The family as proxy." *Pflege Zeit* 67, no. 10 (2014): 600-603.

Bundesministerium der Justiz. "Verfahren nach Betreuungsgesetz 1992–2009." http://www.bmj.de/SharedDocs/Downloads/DE/pdfs/Betreuungsgesetz_Verfahren.html).

Busnelli, Francesco D. "Problemi giuridici di fine vita tra natura e artificio" *Rivista di Diritto Civile* 57, no. 2 (2011): 153-172.

Canestrari, Stefano. "Le diverse tipologie di eutanasia: una legislazione possibile." *Rivista Italiana di Medicina Legale* 25, no. 5 (2003): 751 - 775.

Carmel, Sara and Elizabeth J. Mutran. "Stability of Elderly persons' expressed preferences regarding the use of Life-Sustaining Treatments." *Social Science & Medicine* 49, no. 3 (1999): 303-311.

Catania, Chiara and others. "Opinions concerning Euthanasia, Life-Sustaining Treatment and Acceleration of Death: results of an Italian Association of Medical Oncology (AIOM) survey." *Annals of Oncology : Official Journal of the European Society for Medical Oncology / ESMO* 19(11) (2008) 1947–1954.

Corda, Ilara. *Amministrazione di sostegno, interdizione e inabilitazione. Questioni processuali.* Milano: Giuffre, 2010.

Cohen-Mansfield, Jiska and others. "The decision to execute a durable power of attorney for health care and preferences regarding the utilization of life-sustaining treatments in nursing home residents." *Archives of Internal Medicine* 151, no. 2 (1991): 289-294.

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

Cranford, Ronald E. and David R. Smith. "Consciousness: The most critical moral (constitutional) standard for human personhood." *American Journal of Law and Medicine* 13, no. 2-3 (1987): 233-248.

D'Avack, Lorenzo. "Il disegno di legge sul consenso informato all'atto medico e sulle dichiarazioni anticipate di trattamento, approvato al senato, riduce l'autodeterminazione del paziente e presenta dubbi di costituzionalità." *Il Diritto di Famiglia e delle Persone* 38, no. 3 (2009): 1281-1299.

De Boer Marike E. and others. "Advance Directives in Dementia: Issues of Validity and Effectiveness." *International Psychogeriatrics* 22, no. 2 (2010): 201-208.

De Luca, Federica, and others. "Il disegno di legge circa le disposizioni anticipate di trattamento (alla luce delle modifiche del testo emanato dalla camera il 12 luglio 2011)." *Rivista Italiana di Medicina Legale e del Diritto in Campo Sanitario* 33, no. 3 (2012): 1062-1077.

Department of Health "End of life care strategy: promoting high quality care for all adults at the end of life". https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/136431/End_of_life_strategy.pdf

Dupont, Bernard M. "Refuse a 'Vincent Humbert law'." *Médecine Palliative* 4, no. 6 (2005): 309-311.

Dworkin, Ronald. "Autonomy and the Demented self." *Milbank Quartely* 64, no. 2 (1986): 4-16.

Epstein, Ronald M. "Whole mind and shared mind in clinical decision-making." *Patient Education and Consulting* 90, no. 2 (2013):200-206.

Erin, Charles A. and John Harris. "Living Wills: Anticipatory Decisions and Advance Directives." *Reviews in Clinical Gerontology* 4, no. 3 (1994): 269 – 275.

Frolik, Lawrence A. "Is a Guardian the Alter Ego of the Ward?" *Stetson Law Review* 37, no. 53 (2007-2008): 53-86.

Fine, Robert L. "Ethical issues in artificial nutrition and hydration." *Nutrition in clinical practice* 21, no. 2 (2006): 118-125.

Gardiner Clare and others. "Exploring the transition from curative care to palliative care: a systematic review of the literature." *British Medical Journal of Supportive & Palliative Care* 20, no. 1, (2011): 56–63.

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

Geppert, Cynthia MA, and others. "Ethical issues in artificial nutrition and hydration: a review." *Journal of Parenteral and Enteral Nutrition* 34, no. 1 (2010): 79-88.

Giger, Joyce N. and others. "Multi-cultural and multi-ethnic considerations and advance directives: Developing cultural competency." *Journal of Cultural Diversity* 13, no. 1 (2006): 3–9.

Giunta, Fausto. "Diritto di Morire e Diritto Penale. I termini di una Relazione Problematica.", *Rivista Italiana di Diritto e Procedura Penale* 50, no. 1 (1997): 74 – 125.

Goldberg, Jaime H. "Family Carers in Palliative Care: A Guide for Health and Social Care Professionals." *Journal of Palliative Medicine* 13, no. 3 (2010): 339–340.

Gorgoni, Antonio. "Amministratore di sostegno e trattamenti sanitari." *Europa e Diritto Privato* 14, no. 2 (2012): 547-616.

Grande, Giuseppe and others. "Supporting lay carers in end of life care: current gaps and future priorities" *Palliative Medicine* 23, no. 4 (2009): 339–344.

Guarnieri, Attilio. "Profili Giuridici della Fine della Vita Umane." *Responsabilità Civile e Previdenza* 34, no. 9 (2009): 1707 – 1726.

Higginson, Irene J., and others. "Priorities for treatment, care and information if faced with serious illness: a comparative population-based survey in seven European countries." *Palliative medicine* 28, no. 2 (2014): 101-110.

Holley, Jean L. "Palliative care in end-stage renal disease: focus on advance care planning, hospice referral, and bereavement." *Seminars in Dialysis* 18, no. 2 (2005): 154–156.

Horn, Ruth J. "Advance Directives in English and French Law: Different Concepts, Different Values, Different Societies." *Health Care Analysis : HCA : Journal of Health Philosophy and Policy* 22, no. 1 (2014): 59–72.

Hoppe Nils and José Miola. *Medical law and medical ethics*. Cambridge: Cambridge University Press, 2014.

Hudson, Peter and Sheila Payne. "Family caregivers and palliative care; current status and agenda for the future." *Journal of Palliative Medicine* 14, no. 7 (2011): 864–869.

Iasevoli, Mario "*Decisioni ed Opinioni nel Fine Vita: Confronto tra i diversi Professionisti coinvolti nell'Assistenza al Paziente. Lo Studio Pilota E.L.D.Y.*" (PhD Thesis in Scienza Geriatriche ed Ematologiche in Università degli Studi di Padova, Scuola di dottorato di ricerca in science mediche, cliniche e sperimentali) 2013.

Infantino, Daniela. "Direttive anticipate a amministrazione di sostegno." *La Nuova Giurisprudenza Civile Commentata* 27, no. 6 (2011): 487-492.

ISTAT. "Separazioni e divorzi in Italia" http://www.istat.it/it/archivio/126552

Italian National Bioethics Committee, *Dementia and Alzheimer: ethical consideration.* Roma, 2014.

Italian National Bioethics Committee, *Consciousness objection and bioethics.* Roma, 2012.

Italian National Bioethics Committee, *Conscious withholding or withdrawing medical treatments in the patient-physician relationship*. Roma, 2008.

Italian National Bioethics Committee, *Alimentation and the nutrition and hydration for patients in a persistent vegetative state.* Roma, 2005.

Italian National Bioethics Committee, *Advance directives.* Roma, 2003.

Italian National Bioethics Committee, *Bioethical issues regarding end-of-life.* Roma, 1995.

Italian Society for Anastasia Analgesia Resuscitation and Intensive Care. *Disposizioni in materia di alleanza terapeutica, consenso informato e dichiarazioni anticipate di trattamento (DAT),* Memoria audizione Senato della Repubblica Commissione Igiene e Sanità – 29 settembre 2011.

Italian Society of Anaesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) *"End-of-life, vegetative state, nutrition and hydration"*. 2009.

Italian Society of Anaesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) *"End-of-life and the intensivist: SIAARTI recommendations on the management of the dying patient".* 2006.

Italian Society of Anaesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) *"Grandi insufficienze d'organo "end stage": cure intensive o cure palliative? "Documento condiviso" per una pianificazione delle scelte di cura"*. 2013.

Italian Society of Parenteral and enteral nutrition. *Precisazioni in Merito alle Implicazioni Bioetiche della Nutrizione Artificiale.* http://www.sicp.it/sites/default/files/Precisazioni.pdf

Joint Committee on the Draft Mental Incapacity Bill. *Draft Mental Incapacity Bill* (1st Report, Session 2002-03, HL 189-I), http://www.publications.parliament.uk/pa/jt/jtdmi.htm.

Jox, Ralf J. and others. "Substitute decision making in medicine: comparative analysis of the ethico-legal discourse in England and Germany." *Medicine, Health care, and Philosophy* 11, no. 2 (2008): 153-163.

Kapp, Marshall B. "Commentary, "Anxieties as a Legal Impediment to the Doctor-Proxy Relationship." *Journal of Law, Medicine & Ethics* 27, no. 1 (1999): 69-73.

Karasz Alison, and others. "The rational choice model in family decision making at the end of life." *The Journal of Clinical Ethics.* 21, no. 3 (2010): 189-200.

Kelk, Constantijn. "Previously expressed wishes relating to end of life decisions." In: In *Health law, Human Rights and the Biomedicine Conention: essays in honour of Henrietee Roscam Abbing*, edited by Gevers Sjef K.L. and others, 131 - 145. Leiden: David Adams, 2005.

Kim, Scott Y. H. and others. "Surrogate consent for dementia research: a national survey of older Americans." *Neurology* 72, no. 2 (2009): 149–155.

King, Deborah A. and Timothy Quill. "Working with families in palliative care: One size does not fit all." *Journal of Palliative Medicine* 9, no. 3 (2006): 704–715.

Lagerspetz, 0lli "The Notion of Trust in Philosophical Psychology." In *Commonality and Particularity in Ethics,* edited by Alanen, Lilli and others, 95-117. New York: St. Martin's Press, 1997.

Letsas, George. "Strasbourg's Interpretive Ethic: Lessons for the International Lawyer." *European Journal of International Law* 21, no. 3 (2010): 509-541.

Manson Kenyon and Graeme Laurie. *Mason and McCall Smith's Law and Medical Ethics.* Oxford: Oxford University Press, 2011.

Maltese, Domenico. "Il Falso Problema della Nutrizione Artificiale." *Il Foro italiano* 134, no.4 (2009): 987 – 989.

Marion, Danis and others. "Stability of Choices about Life-Sustaining Treatments." *Annals of Internal Medicine* 120, no. 7 (1994): 567-573.

Masoni, Roberto. "I testimoni di Geova tra Legittimità, Merito ed Amministrazione di Sostegno." *Diritto Famiglia e delle Persone* 38, no. 1 (2009): 58 – 73

Meisel, Alan. "Legal myths about terminating life support." *Archives of Internal Medicine* 151, no. 8 (1991): 1497-1502.

Menaca, Arantza and others. "End-of-life Care across Southern Europe: a Critical Review of Cultural Similarities and Differences between Italy, Spain and Portugal." *Critical Reviews in Oncology/Hematology* 82, no. 3 (2012): 387-401.

Miccinesi, Guido and others. "Continuous Deep Sedation: Physicians' Experiences in six European countrie." *Journal of Pain and Symptom Management* 31, no. 2 (2006): 122–129.

Molaschi, Viviana. "Withdrawal of Artificial Hydration and Nutrition from a Patient in a Permanent Vegetative State in Italy: some considerations on the Englaro case." *Italan Journal of Public Law* 5, no. 2 (2012): 122-158.

Mollaret Pierre and Maurice Goulon "Le coma dépassé." *Revue Neurologique* 101, no. 1 (1959): 3-15.

Neitzke, Gerald and others. "Göttinger Thesen zur gesetzlichen Regelung des Umgangs mit Patientenverfügung und Vorsorgevollmacht." *Ethik in der Medizin* 18, no. 2 (2006): 192–194.

Neri, Demetrio. "Autonomia e Dignità della Persona alla Fine della Vita. Chi decide?" In *Autonomia e limite. Siamo liberi di scegliere*?, edited by Commissione Bioetica della Tavola Valdese - AA.VV. - Luca Savarino (Piacenza: Vicolo del Pavone 2010).

Parfit, Derek. *Reasons and Persons*. Oxford: Oxford University Press, 1984.

Pasquino, Teresa. *Autodeterminazione e dignità della morte*. Padova: Cedam, 2009.

Pereira, Ray. "Human handicap and self-determination: compassion and insensibility in the Vincent Humbert case." *História, Ciências, Saúde-Manguinhos* 14, no.1 (2007): 119-134.

Pope, Thaddeus M. "Legal Fundamentals of Surrogate Decision Making", *Chest* 141, no. 4 (2012): 1074–1081.

Powell, Tia. "Extubating Mrs. K: Psychological Aspects of Surrogate Decision Making." *Journal of Law, Medicine* & *Ethics,* 27, no. 1 (1999): 81-86.

Probst, Martin and Bernhard Knittel. "Gesetzliche Vertretung durch Angehörige – Alternative zur Betreuung?" *Zeitschrift für Rechtspolitik* 34, no. 2 (2001): 55-60.

Quill, Timothy E. and others. "The rule of double effect—a critique of its role in end-of-life decision making." *New England Journal of Medicine* 337, no. 24 (1997): 1768-1771.

Quill, Timothy E. "The ambiguity of clinical intentions." *New England Journal of Medicine* 329, no. 14 (1993): 1039-1040.

Rodotà, Stefano. *Perché laico*. Roma-Bari: Laterza, 2009.

Sabatino, Charls P. "The Legal and Functional Status of the Medical Proxy: Suggestions for Statutory Reform." *Journal of Law, Medicine & Ethics* 27, no. 1 (1999): 52-68.

Sahm, Stephan and others. "Attitudes Towards and Barriers to Writing Advance Directives Amongst Cancer Patients, Healthy Controls, and Medical Staff." *Journal of Medical Ethics* 31, no. 8 (2005): 437–440.

Salvatore, Barbara. "Principio di autodeterminazione e decisioni di fine vita" *Rivista di Diritto Privato* 18, no. 1 (2013): 107-133.

Sesta, Michele. "Riflessioni sul testamento biologico." *Famiglia e Diritto* 15, no. 4 (2008): 407-411.

Seymour Jane and others. "Planning for end of life: the views of older people about advance care statements." *Social Science & Medicine* 59, no. 1 (2004): 57–68.

Siegel, Mark D. and others. "Psychiatric Illness in the next of Kin of Patients who die in the Intensive Care Unit." *Critical care medicine* 36, no.6 (2008): 1722-1728.

Sulmasy, Daniel P. "Commentary: Double Effect-Intention is the Solution, Not the Problem." *The Journal of Law, Medicine & Ethics* 28.1 (2000): 26-29.

Technical and Scientific Commisison on "*Vegetative state and minimum conscious state*" established with the Ministerial Decree of 12 September 2005 http://www.aduc.it/generale/files/allegati/cure_stato_vegetativo.pdf

Truog, Robert D. and others. "Recommendations for end-of-life care in the intensive care unit: A consensus statement by the American College of Critical Care Medicine." *Critical care medicine* 36, no. 3 (2008): 953-963.

Vimercati, Benedetta. "Amministratore di sostegno e consenso informato: scelte di politica legislative e case law a raffronto (parte I)." *Rivista Italiana di Medicina Legale e del Diritto in Campo Sanitario* 33, no.1 (2011): 129-173.

Walter, Jennifer K. and Lainie F. Ross. "Relational Autonomy: Moving Beyond the Limits of Isolated Individualism" *PEDIATRICS* 133, no. 1 (2014): S16-23.

Woods Simon. *Death's Dominion: Ethics at the End of Life.* Maidenhead: Open University Press, 2007.

Zullo, Silvia. "Interruzione delle cure e morte cerebrale. Profili bioetici e filosofici." In *Bioetica e Biodiritto Problemi, casi e materiali.*, edited by Carla Faralli, 122 - 131. Torino: Giappicchelli Editore, 2010.

Chapter 4: Conclusions

1. The importance of advance directives in end-of-life decisions

In this thesis the concept of autonomy in end-of-life decisions has been analyzed through ethical and legal approaches. The main aim of it is to demonstrate the strong connection between ethics and law in end-of-life decisions and to show through case-law study the relevance of moral and legal protection of the patient's right to self-determination. In addition, it has evidenced the basic common European standard by examining some of the most important documents published by the Council of Europe. Moreover, it has investigated the reasons for the absence of a uniform approach within some Western European countries by studying the national law of twelve different countries.

The significance of advance directives and the legal situation in Romance-speaking countries (Italy, France, Portugal, and Spain), English-speaking countries (Ireland and the United Kingdom of Great Britain and Northern Ireland), and German-speaking countries (Austria, Germany, and Switzerland) has been studied. Particular attention has been given to the situation in Italy, Spain, France, England, and Germany, since the other countries in this survey have adopted a similar policy or because the legal and ethical discussion is quite complex.

In particular, the Portuguese parliament of 2012 used the Spanish law of November 2002 as a model. The Italian Bill no. 2350 shares its political motivation with the previous version of the French law of 2005. The *Mental Capacity Act* recognizes similar principles with the other English-speaking countries. In the German-speaking countries, national legislators have adopted the same political approach: assuming that end-of-life decisions are an individual matter, they have modified their civil codes. In addition, the German legislator in 2009 adopted a quite liberal approach.

The situation in Italy has been examined in detail, since the bioethical discussion is quite complex, moving from a complete paternalist approach in 1993 to a liberal one in 2014. In addition, the new Italian Code of Medical Ethics of May 2014 adopted a quite paternalistic approach, particularly in comparison with the previous version of 2006. Furthermore, none of the eight new proposal bills presented in the new term of legislation, which started on March 2013, have been discussed by the permanent commissions of the Italian Parliament. Therefore, the Italian Bill 2350 "Provisions relating to therapeutic alliance, informed consent and advance directives for treatments" is the only act which has been debated by the deputies and senators in different texts in 2009 by the Senate and in 2011 by the Chamber of Deputies. Moreover, although Italy is not part of common law system, judges have "created" laws in single cases because they have been called on to strike a balance between patient autonomy and the patient's right to self-determination, on one side, and the application of the paternalist approach to the principle of duty of care, on the other. The jurisprudence has interpreted constitutional rights or has offered extensive interpretation of the existing laws, in particular the one regarding the support guardian.

Less than seventy years ago, end-of-life decisions were considered a taboo subject. This scenario began to change in the late 1960s in the USA, where the individualistic approach is more common, and then in Europe. This was a direct result of the advance in medical discoveries, which entailed a grey zone between life and death: the promulgation of life or the anticipation of death might depend on the individual's or the doctor's decision to inject or reject life-sustaining treatment.

It should be noted that there is no other field like biomedicine, and especially end-of-life decisions, where law and ethics are so closely intertwined. This is also facilitated by the fact that both law and ethics use the same conceptual categories: rules, principles, rights, and procedures. Both of them focus on the protection of patient autonomy and patient rights and not

on ideal situations, but on concrete medical situations. The work of the ethicist is both framed in light of the law and influenced by it.

In the 21st century, ethicists are chosen as experts by courts or by European parliaments to assist with the legal regulation of biomedicine. European legislators have highlighted the close relationship between ethics and law by establishing bioethical committees. When physicians have to deal with terminally ill patients, they do not only need medical knowledge but also legal and ethical expertise. This has recently been confirmed as well by the Council of Europe in the Guide on the decision-making process regarding medical treatment in end-of-life situations.

The increase in medical discoveries, which has led to an increase in life-expectancy and a decrease in sudden death, has stimulated national legislators to rethink the traditional legal norms regarding end-of-life situations. Moreover, the aspect of trust between patient and physician and patient autonomy has been highlighted.

In the past, death and the process of dying were considered a matter of private decision within the specific socio-cultural and religious background; today, end-of-life decisions have become a matter of ethical debate and of public policy. The patient's active role has been acknowledged on both the national and the international level. The bioethical communities as well as courts have highlighted the importance of ADs.

All the Romance-, English-, and German-speaking countries – except Northern Ireland, Ireland, and Italy – have legally backed ADs. Although in Northern Ireland there is no law on ADs, the bioethical community is asking for the implementation of the English Mental Capacity Act of 2005. In Ireland, the Assisted Decision-Making (Capacity) Bill 2013 and the *Advance Healthcare Decision Bill* 2012 are under public consultation. As stated above, the bioethical discussion in Italy is quite complicated.

The patient's active role has been acknowledged in several international conventions, such as the European Convention on Human Rights

(ECHR) of 1950; the Hague Convention on the International Protection of Adults of 13 January 2000; the Charter of Fundamental Rights of the European Union of 2000, which from 1 December 2009 has the same legal status as EU Treaties; and the United Nations' Convention on the Rights of Persons with Disabilities of 13 December 2006. In addition, the Council of Europe has enhanced patient autonomy in end-of-life decisions through the European Convention on Human Rights and Biomedicine of April 1997, the Recommendation CM/Rec (2009) 11 of the Council of Europe, and the Guide on the decision-making process regarding medical treatment in end-of-life situations of May 2014.

In recent decades there has been a transformation of the scope of medicine, from the strict medical concept of health to the broader concept of wellbeing, where shared decision-making – especially as a result of a program of care planning in collaboration and in communication with physicians – is the main goal. This has been highlighted on both the national and the international level.

2. Advance directives within the Council of Europe

The Council of Europe has concerned itself with problems regarding the protection of patient autonomy in end-of-life decisions. The most important documents regarding this issue are the Convention on Human Rights and Biomedicine (also known as the Oviedo Convention) of April 1997, Recommendation CM/Rec (2009) 11 of December 2009 and the *Guide on the decision-making process regarding medical treatment in end-of-life situations* of May 2014. The importance of these documents was recently acknowledged in the last ruling of the ECtHR (Application 46043/14, par. 59, 60, and 69).

The Oviedo Convention should be considered a *lex specialis* of the ECHR of 1950. The Oviedo Convention has therefore implemented the ethical principles of autonomy, beneficence, non-maleficence, and justice –

established in general in the ECHR – in the biomedical field. Specifically, the principle of autonomy – established in Article 8 of the ECHR – has been recognized in Articles 5 and 6 of the Oviedo Convention. Articles 2 and 3 of the ECHR, which recognized the principles of beneficence and non-maleficence, have been transferred to Articles 2 and 4 of the 'new' convention. In addition, the Oviedo Convention has added the principle of justice (Article 3), which was further developed in Recommendation (2003) 24 of the Committee of Ministers of the Council of Europe on the organization of palliative care.

The European Convention on Human Rights and Biomedicine is the first international legally binding comprehensive multilateral treaty addressing human rights issues in biomedicine. It provides basic standards in the biomedical field that have been recognized as fundamental by the European Court on Human Rights. In addition, it avoids economic competition in biomedical research and stimulates public debate and political agreement in the field of biomedicine.

It must be noted that the Oviedo Convention recognizes the importance of advance wishes through Article 9, where it is established 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*." This convention does not specify what "shall be taken into account" means. The only interpretation of this phrase comes from its Explanatory Report, which states: *"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*" (par. 62).

It should be noted that the previous version of the Oviedo Convention used the word *decisive*, but since this adjective created several problems, the final version of it substituted this term with the version "*the previously expressed wishes* [...] *shall be taken into account*." Nevertheless, this does not mean that previously expressed wishes should be simply considered as the patient's orientation. In addition, the physician should have convincing arguments in order to not follow patient's directives.

While the Convention on Human Rights and Biomedicine of April 1997 dedicates only one article (Article 9) to ADs, Recommendation CM/Rec (2009) 11 and the "Guide on the decision-making process regarding medical treatment in end-of-life situations" focus on ADs and end-of-life situations in general.

2.1. The application of Recommendation CM/Rec (2009) 11 of the Council of Europe as a source of law

It has been demonstrated, by giving concrete examples from the national legislation of twelve different European countries, that Recommendation CM/Rec (2009) 11 could be applied by the ECtHR as a source on which to base its decisions. Therefore, the fact that this document is an example of so-called *soft law* does not influence this conclusion, because this document shows the common European principles on end-of-life decisions, which are shared by all the English-, German-, and Romance-speaking countries.

The significance of this recommendation lies in the fact that it recognizes the role of the legal proxy appointed by the citizen. While the Oviedo Convention recognizes only *previously expressed wishes*, Recommendation CM/Rec (2009) 11 acknowledges that autonomy – especially if understood in its etymological meaning – is merely an ideal. Citizens have difficulties in foreseeing all the possible diseases that entail incapacity and all medical treatments that could be used in these cases. This is a direct result of the absence of medical knowledge or of advances in medicine. It follows that the power of attorney, especially in case of the grantor's incapacity, is fundamental.

The human person is a subject in a determinate environment. External factors – especially personal relationships – influence human personality. Recommendation CM/Rec (2009) 11 underlines these influences by considering the role of the legal proxy. Unlike Recommendation (99) 4,

Recommendation CM/Rec (2009) 11 prioritizes the appointment of a surrogate (named by the citizen) rather than that of a guardian (chosen by a public organ). This reflects the trend in legislation towards giving priority to the establishment of private continuing powers of attorney over public measures.

The appointment of a legal proxy has been highlighted by different national legislators. For instance, in Austria, the legislator in 2006 modified the Civil Code, the *Allgemeines bürgerliches Gesetzbuch* (ABGB), only regarding the appointment of the surrogate; an *ad hoc* law – which is not part of the ABGB – regulates "living wills." In Germany, the legal proxy (*Betreuer* or *Bevollmächtigter*) must examine whether the determinations made in the living will correspond to the current living and treatment situation (Article 1901a, section 1 BGB). In England and Wales, Article 25, section 2, lett. b) of the MCA 2005 states that a previous "living will" is not valid if the donor, having written the "living will," has created a lasting power of attorney which confers authority on the donee to give or refuse consent to the treatment to which the advance decision relates. Recently, the French legislator in March 2015 modified Article 1111-4 of the CSP; the new version states that in case of hospitalization, it is proposed to the patient to appoint a surrogate.

Also, in the Romance-speaking countries, national legislators have modified their civil codes to give an opportunity to citizens to give power of attorney to others; this power remains valid even in case the grantor should lose his or her full competency (France, Article 477 CC; Italy, Article 408 CC; Portugal, Article 1175 CC; Spain, Article 1732 CC).

Recommendation CM/Rec (2009) 11 established several principles that are commonly shared in all parliaments in English-, German-, and Romance-speaking countries. Therefore, the ECtHR could apply this recommendation, even though is *soft law*, as it did with the European Convention on Human Rights and Biomedicine when it was not ratified (Application no. 61827/00 and no. 53924/00) or with Recommendation R (99) 4 (Application no. 44009/05).

2.2. Comments regarding the Guide on the decision-making process regarding medical treatment in end-of-life situations of May 2014

The aim of the commentary on the *Guide on the decision-making process regarding medical treatment in end-of-life situations* (the *Guide*) is to underline the significance of this document in turning our attention back to the application of the patient-centered approach and to emphasize the role of the patient's family and relatives. However, the main critiques made in this scientific work regard the fact that this document should also have included guidelines regarding cases of euthanasia or PAS. In addition, the *Guide* should have given a definition of "vegetative state" and "futile treatment."

Although this *Guide* regards end-of-life situations, euthanasia or PAS are not covered. The *Guide* could have encompassed them because some national parliaments – like those of the Netherlands, Belgium, Luxemburg, and Switzerland – have legally regulated PAS or euthanasia. Recently, in November 2015, the German Parliament has modified Article 217 of the Criminal Code by regulating assisted suicide. It follows that in countries where there is no *ad hoc* legislation regarding these medical practices – but nevertheless some physicians are practicing them (illegally), since they would like to relive patients from the suffering and there exist a will of the patient in that regard – physicians do not have any guidelines to follow. Therefore, physicians will perform them according to their personal ethical convictions. This increases the physicians' discretion in addition to the uncertainty regarding the modalities of these practices.

Moreover, the *Guide* does not consider cases of vegetative state or what "medical futility" means. Since the focus of this *Guide* is on helping the care team to combine medical information with ethical principles, and since physicians have to deal with these cases daily, it would have been appropriate for the Council of Europe to establish guidelines or give definitions regarding

these issues in this document. Moreover, the medical debate regarding these issues was recently brought to the attention in the case law in *Lambert*, where the *Conseil d'État* and then the ECtHR had to consider whether withdrawing artificial nutrition and hydration from a patient in a vegetative state should be deemed futile treatment.

The *Guide* recognizes the importance of clinical ethics committees and of a review of previous decisions. A review of previous decisions could help the process of end-of-life situations. The intention of this review should not be to control the work done by the care team but to assist them in making better decisions in the future. Based on the results of these studies, healthcare facilities could organize seminars or training programs addressing the complexity of end-of-life decisions.

Furthermore, the *Guide* pays particular attention, without taking any official position, to the ethical debate regarding cases of withdrawal of ANH. The *Guide* does not take any official position regarding this issue, because there is no general agreement among the member States of the Council of Europe on the withdrawal of ANH. For instance, French, Italian, and English legislators have *ad hoc* rules regarding this issue. In France, ANH will be withdrawn – after applying the collegial proceeding established in Article 37 of the Code of Medical Ethics – if the treatment has no effect other than the artificial prolongation of life (Article 1111-5-1 CSP). In Italy, ANH must be maintained until the end of life, except in cases where it is no longer effective in providing the patient with the nutritional elements necessary for the essential physiological functions of the body. Moreover, ANH cannot be withdrawn through ADs (Article 3, section 3 Bill 2350 repeated in the same form by Proposal Bill 2229 of 26 March 2014). In England and Wales, life-sustaining treatment – and therefore also ANH – can be withdrawn through ADs if that is stated in writing and signed by the *donor* or by somebody else in the donor's presence or under his or her directives (Article 25 of the Mental Capacity Act).

Although the *Guide* does not take any official position regarding this debated bioethical topic, its usefulness consists in underlining that ANH cannot be qualified as basic care, because it states that this technique implies choices concerning medical procedures and devices. This is important because some official documents – such as *Alimentation and nutrition and hydration for patients in a persistent vegetative state*, published by the Italian Commission on Bioethics in 2005; or the conclusions published by the Technical and Scientific Commission on the *Vegetative state and minimum conscious state* established with the Italian Ministerial Decree of 12 September 2005; or Italian Bill 2350 or Proposal Bill 2229 – recognize that nutrition through medical machines constitutes basic care.

The *Guide on the decision-making process regarding medical treatment in end-of-life situations* applies an interdisciplinary reasoning which could effect the decisions of the care team and also of the patient's legal proxy, family, and relatives. Generally, national laws in English-, German-, and Romance-speaking countries are in harmony with these guidelines.

3. Comparison between English-, German-, and Romance-speaking countries

The aim of this survey is to understand the reasons for the absence of a homogeneous framework in end-of-life decisions and to investigate the moral values that national policies have protected. A division has been made based on the level of protection of patient autonomy and the role of physicians in end-of-life situations. As a result of the application of these criteria, the Romance-speaking countries differ from the English- and German-speaking countries, since in the first group of countries, national legislators have also highlighted the importance of the role of physicians.

The national policies that have been analyzed in detail are those of Spain, France, England, and Germany. These policies have been considered as paradigm cases, since the other countries in this thesis take a similar legal,

ethical, or political approach to one of these. Although all these countries emphasize the importance of the patient's right to self-determination, in Romance-speaking countries the ethical principles of beneficence and non-maleficence are legally acknowledged as well.

In all the English-, German-, and Romance-speaking countries examined, ADs are considered an instrument that supports a broad concept of patient autonomy. All these countries have recognized the importance of both "living wills" and "surrogate wills." Furthermore, all – except Ireland, Italy, and Northern Ireland – have enacted national legislation on end-of-life decisions.

In Spain, measures contrary to the *lex artis* – understood as "good medical practices" – may not be applied. Although in most countries directives against "good medical practices" will not be executed, the Spanish Parliament has explicitly specified this in the law. The General Council of Medical Colleges, which represents all physicians in Spain, is responsible for defining the meaning of "good medical practices." In addition, prior instructions that do not correspond to the situation the "interested party" considered at the moment of stating them are not executed. Since the law does not define the person responsible for examining whether these prior wishes correspond to the current living and treatment situation, and because "living wills" are documents used to consolidate the patient-physician relationship, it can be concluded that in Spain the execution of a living will depends on the interpretation of the physician in charge.

In France, under the influence of Rousseau's philosophy of the social contract, physicians consider themselves to be representatives of the society who should make rational decisions on behalf of the ill. Therefore, physicians are obliged to do everything possible to convince the competent patient not to refuse medical treatment. Moreover, French law prioritises a physician-centred approach by explicitly establishing in the law an *ad hoc* collegial procedure in cases involving a limitation or withdrawal of life-sustaining or life-prolonging treatment if there is an imminent risk of death. This policy has

been confirmed by the legislator in March 2015, where the new Article 1111-5-1 CSP establishes the *ad hoc* collegial procedure in the case of withdrawal of treatments that do not have any benefits other than keeping the patient artificially alive. Furthermore, the French National Medical Council has the power to implement the French Public Health Code through its Code of Medical Ethics. Although these rules are primarily relevant in disciplinary proceedings, the French Council of State – after judicial review – can adopt those regulations as national law.

In German- and English-speaking countries, the patient's right to self-determination constitutes the main focus of national legislation. End-of-life decisions are considered a private matter, and a court decision is required only in situations explicitly defined by national laws. For instance, in England the intervention of the Court of Protection is needed only when there is a conflict regarding the patient's best interest – a concept that in England also refers to the patients' past and present wishes and feelings – or the patient's medical treatment. On the other hand, in Germany the Court of Guardianship is required to rule only if there is a conflict between the legal proxies and the physicians responsible for issues of consent, refusal, or revocation of former consent. In addition, in both countries, judges must base their decisions on the patient's previous wishes.

All the Western European countries mentioned have recognized the patient's right to self-determination. Nevertheless, national parliaments in the Romance-speaking countries have adopted a physician-centred approach, since in these countries physicians have higher obligations to protect patients. In England and in Germany, national laws do not rely on physicians' decisions and confer this power on medically neutral persons. In those countries, this is considered the best way to protect patient autonomy against the interests of physicians, who in the past have been criticized for paternalism. Among the countries analysed, the German parliament has adopted the most liberal approach.

4. Possible modification of the Italian bill regarding "advance directives"

Within the countries surveyed, the Italian situation in end-of-life scenarios is the most complex because Italy is one of the few Western European countries that lack an *ad hoc* law regulating ADs. Moreover, the Italian bioethical and medical communities have adopted controversial positions. In addition, the jurisprudence has filled the gap of the absence of legal norms governing advance directives by applying constitutional rights or by making an extensive interpretation of existing legal rules. Furthermore, Bill no. 2350 is the only bill discussed by Italian senators and deputies, since the eight proposal bills of the new legislature, which started on 15 March 2013, have not been discussed yet by the Parliament's permanent commissions.

In Italy, the most important case law is that of *Englaro*. As in the other major case law – such as *Schiavo* and *Bland*, and recently *Lambert* – the central question regards the relation between the sanctity of life and quality of life. In all these cases, judges have highlighted patient autonomy by giving patients the right to self-determination according to their values, even after they have become unconscious. It should be noted that this ruling introduced in Italy the doctrine of substitutive judgment. Moreover, the same legal reasoning applied in this ruling was recently applied by the Italian Council of State in its ruling of 2 September 2014, no. 4460.

Since the ruling regarding *Eluana Englaro*, the Italian Parliament has tried to pass legislation on end-of-life decisions. Until now, Bill no. 2350 "*Provisions relating to therapeutic alliance, informed consent, and advance directives for treatments*" is the only act which has been debated by Italian deputies and senators. The paternalist approach of this bill has been recently confirmed by one of the latest proposals – Proposal Bill no. 2229, proposed by Ms. Roccella and others on 26 March 2014 – and in Article 38 of the new Italian Code of Medical Ethics of May 2014.

Italy should have a specific law governing end-of-life decisions. This need has been highlighted by both the bioethical and the medical community. Moreover, recent studies have demonstrated that Italian citizens – like other western European citizens – prioritize the quality of life rather than an extension of life. Therefore, although national legislators have applied different policies, citizens' preferences and values in regard to end-of-life situations are similar.

The Italian Parliament should adopt a bioethical approach based on informed consent and on care planning where the patient-physician trust should be considered essential. This law should be "reasonable," in addition to governing end-of-life situations by paying particular attention to patient autonomy and the patient's right to self-determination. Moreover, this law should reflect the particular cultural aspect of Italian society and should also examine suggestions coming from the main medical scientific organizations, such as SIAARTI and FNOMCeO.

In addition, the law should take into account the rulings of the Italian Constitutional Court and of Italian judges, who until now have substituted the Italian legislator by ruling on individual cases protecting patient autonomy and the right to self-determination. Moreover, differently from Bill 2350, the law must not be a political reaction and must be relevant.

ADs should be without restriction in time or object and must be applied even in cases where there is a risk of death. This is a direct result of the application of the ethical principle of patient autonomy and the right to self-determination in healthcare treatments, which is recognized as a constitutional right through the combination of Articles 13 and 32 of the Italian Constitution. The restriction in time or object would be considered a paternalist approach that would not be consistent with the protection of the patient's wellbeing – a concept with is broader than the patient's health – and would compromise the patient-physician trust.

Furthermore, particular attention should be paid to the different uses of the medico-legal notions of "advance directive" and "living will," terms

correctly used by the Italian National Committee in its document published in 1993. In accordance with the *Advanced Statements about Medical Treatment* published by the British Medical Association in 1995, it is the "living will" – not the broader concept of "advance directive" as stated in the Italian Bill – that is the formal declaration written by a competent adult conveying her or his wish for any life-prolonging measures to be withheld in circumstances where there is no prospect of recovery.

Also, a correct interpretation of the international framework – the Convention on the Rights of Persons with Disabilities – is needed. Article 25 of this Convention envisages cases where patients with disabilities request medical treatments, not cases where patients refuse them through "living wills" when they were of sound mind. Moreover, it is descriptively inaccurate to refer to a person in a vegetative state as being disabled, since between the two conditions there are more differences than similarities.

The Italian law should consider the fact that the majority of Italian physicians (SIAARTI and FNOMCeO), Italian jurisprudence (the case law in *Eluana Englaro*), and the Oleari Commission (formed by the Minister of Health in the year 2000) consider medical nutrition as medical treatment, because the delivery method is artificial. This principle has been clearly established by the British Medical Association in its document of 2007, *Withholding and Withdrawing Life-Prolonging Medical Treatment Guidance for Decision Making*. In addition, it seems that the same reasoning has been recently used by the Council of Europe in the Guide on the decision-making process regarding medical treatment in end-of-life situations of May 2014, since it states that this technique entails choices concerning medical procedures and devices. Moreover, the medical staff has proven that death due to dehydration is palliative.

Solutions regarding the withdrawal of treatments come from the bioethical community or from the experience of other Western European countries. The bioethical community has stated that physicians should not focus on the abstract quality of ANH, but should rather answer the question of

the extent to which this treatment benefits a *specific* patient in a *specific* condition. In the Netherlands, feeding a patient through a tube is deemed a medical act, which can be halted on the ground of its *senseless* nature. The classification of ANH as a *senseless medical act* under certain conditions avoids the ambiguous legal consequences that come from its classification as basic care or medical treatment. Thus, there is no need for legal qualification, and medical consideration, based on current medical ethical standards, becomes crucial.

In the UK, the MCA gives the agent the possibility to include a refusal of ANH in his or her treatment directives, but not a refusal of natural nutrition and hydration. Therefore, medical nutrition and hydration can be refused. Instead, the new French law of March 2015 has established – in its Article 1110-5-1 CSP – an *ad hoc* collegial procedure in cases of withdrawal of treatment that do not have benefits other than keeping the patient artificially alive.

The problem of withdrawing ANH has been highlighted by some of the new proposal bills. While Proposal Bill 2226 has adopted the same paternalist approach as BILL 2350, Proposal Bills 1298, 1432, and 2264 have established that ANH can be withdrawn. On the other hand, Proposal 443 states that parental feeding is not deemed futile treatment. This proposal has codified the controversial discussion within the bioethical community, where a distinction between gastrostomy and nasogastric feeding has been underlined. It should be noted that the entire bioethical community accepts gastrostomy feeding as a medical treatment, but some scholars have raised doubts regarding the definition of nasogastric feeding as such. However, these scholars recognize nasogastric feeding as a general medical management.

ADs could be written even without full medical and clinical information, a requirement that belongs more to the world of bureaucracy than to that of a concrete medical situation. What follows is an increased public trust in these kinds of documents and a decrease in the public expenditure regarding the cost that physicians or hospitals need to make to implement this policy.

Furthermore, oral medical declarations made under certain circumstances should be considered valid. Therefore, people that are incapable of writing – probably for physical problems – should still be able to formulate a "living will." This would be a direct application of the constitutional right to equal treatment (Article 3 of the Italian Constitution) and a better application of the Convention on the Rights of Persons with Disabilities of 13 December 2006, ratified in Italy by Law no. 18 of 3 March 2009. Of all the new proposal bills, Proposal Bill 13 is the only one that takes this principle into account. It states that oral declarations received by the physician or clearly documented through video recording are valid (Article 23, section 1, lett. d).

ADs should not be time-limited. However, the Italian medical community (SIAARTI and FNOMCeO) has underlined the importance of a revision of ADs. According to them, an update of ADs will make ADs less ambiguous and more coherent with the current medical situation and with patient wishes. Bill 2350 and Proposal Bill 2229 have codified this concern by limiting the validity of ADs to five years after they are written.

Although these concerns are shared, they should be a suggestion, not a legal requirement. The problems derived from the long period that can pass between the formulation of ADs and their execution could be resolved by taking into consideration the models derived from the Explanatory Report of the Oviedo Convention or from German and French laws. According to paragraph 62 of the Explanatory Report on the Convention on Human Rights and Biomedicine, ADs are valid until the moment there is a medical discovery or a change in the patient's pathology such that the patient would have changed his or her medical instructions had he or she become aware of them. This seems to be the policy adopted by Proposals 13, 1432, 1298, and 2264. Instead, the German and French Parliaments have resolved the uncertainty of personality changes entailed by the absence of this temporal limitation by giving broader powers to the surrogate, who must verify whether the instructions contained in a living will adequately address the current medical

situation. This has been established in Article 1901a, section 1 BGB, and in Article 1111-6, section 2, CSP.

The Italian legal system needs clear rules for advance medical declarations. The law must consider the international framework, as well as domestic rulings in Italian jurisprudence, without forgetting the ethical principle of autonomy.

4.1. Possible modification of the Italian bill regarding "surrogate wills"

The main aim of this paragraph is to highlight the key role of a legal proxy in ascertaining the medical directive of an unconscious patient. With the aim to supporting this result, arguments on moral reasons have been given. In addition, it has examined concrete legal examples established in the legislations of Germany, France, and England. In the conclusions, the difference between the legal figure of the surrogate (the legal proxy appointed by the citizen) and that of the support guardian (the legal proxy appointed by the judge under Article 404–413 C.C.) in the Italian legal system has been explained. It has been argued that, if certain conditions are satisfied, a support guardian can be appointed even if the citizen is still conscious.

In end-of-life decisions, the appointment of a legal proxy is considered fundamental. Their appointment should be considered the best option for resolving well-documented problems that arise with the interpretation of fixed documents written at a particular time. National legislators and court rulings have contemplated this fact. Recently, this has been confirmed in France. The results from the latest empirical research conducted there and published in 2015 show that the appointment of a surrogate has been reported three times more often than the formulation of a "living will." In addition, the new law of March 2015, *Loi créant de nouveaux droits en faveur des malades et des personnes en fin de vie*, has modified Article 1111-4 CSP by

establishing that in case of hospitalization, the medical staff must ask the patient if he or she would like to appoint a legal representative.

The Italian parliament must recognize the importance of the role of the surrogate. The experience derived from other Western European countries, and especially the MCA of 2005, should be taken into consideration. The Italian law should offer a chance to appoint more than one surrogate. The ability to appoint several surrogates could be a fair solution in cases where there are several children involved. In addition, two or more surrogates may be the answer to an undue concentration of power or to the need to reduce the risk of family dispute. Unfortunately, neither the Italian Bill no. 2350 nor the other eight new proposal bills regarding end-of-life decision-making offer this possibility.

In addition, specific sanctions should be stated in cases involving surrogates that ignore the obligations established in the law. Moreover, an authority to oversee the surrogate's activity and to rule in cases of conflict between surrogates and doctors should be considered. The establishment of an authority empowered to resolve disagreements between surrogate and physician and to oversee the surrogate's activity is important, since empirical studies have shown that some surrogates – due to clinically diagnosed conditions, such as stress, depression, and anxiety – could loose their capacity or may sometimes have dubious motives in that they are looking out for their own interests rather than for those of the patient. In case of conflict between surrogates and doctors, two different solutions could be used. The first is to resolve the conflicts within the hospital, as established in Proposals 5 and 1142 and suggested by SIAARTI; the second is to resort to a judge, as established in Proposals 13, 443, 1298, and 2264. While the first approach yields a more expedited decision based on medical criteria, the second model is fully impartial.

This authority should be impartial and exercised by a judge who is specialized in this field. Therefore, the proceeding will be swifter and less complex and/or expensive. Since the Italian constitution recognizes the right

to justice (Article 24), the same result would probably be achieved through the appointment of an external expert; but this will make the process longer, more expensive, and more complex. It should be noted that in end-of-life situations the decision by the judge should be quick, and ordinary jurisdiction – even in cases of summary procedures introduced by Law 69 of 19 June 2009 – cannot provide that.

The legal roles of guardian and surrogate are similar but not identical. Surrogate and guardian alike must decide according to the patient's preferences and values. Both are designated by the patient, but as the High Court of Cassation ruled in 2012, only a judge can appoint a guardian when the ward cannot do so. Moreover, the instructions contained in the "guardian will" are legally binding only between citizens; the judge is only required take them into account in arriving at a decision. Additionally – if there is a serious reason – the judge has the power to dismiss the guardian.

Until then, Italian judges should protect the patient's autonomy without conflating the legal figure of a guardian with that of a surrogate: an extended interpretation of Articles 404–413 C.C. in light of the constitutional right to self-determination can be applied. When citizens are fully competent, a guardian could be appointed – and not only designated – only in cases where, in the near future, incapacity is almost certain and patients have received detailed information about the medical consequences of their disease.

5. Final remarks

In this thesis, it has been argued that in end-of-life decisions law and ethics are closely intertwined. Both focus on the protection of patient autonomy and therefore on the patient's right to self-determination in concrete medical situations. The work of the ethicist is both framed in light of, and influenced by, the law.

On the European level, the most important documents regarding this issue are the Convention on Human Rights and Biomedicine of April 1997, Recommendation CM/Rec (2009) 11 of December 2009, and the Guide on the decision-making process regarding medical treatment in end-of-life situations of May 2014.

By giving concrete examples from the national legislation of the English-, German-, and Romance-speaking countries, it has been shown that Recommendation CM/Rec (2009) 11, though it is considered an example of *soft law*, could be applied by the ECtHR as a source on which to base its decisions.

The commentaries on the *Guide on the decision-making process regarding medical treatment in end-of-life situations* has demonstrated the application of the four ethical principles in end-of-life issues. However, it has been suggested that guidelines regarding euthanasia or PAS be included, since several countries have regulated them, in addition to the fact that several studies have shown their use even in countries where there is a lack of legislation or where these medical practice are deemed illegal.

By focusing on the legal situation in English-, German-, and Romance-speaking countries, it has been noticed that in all them, advance directives are considered an instrument that supports a broad concept of patient autonomy. All these countries have recognized the importance of both "living wills" and "surrogate wills." Furthermore, all – except Ireland, Italy, and Northern Ireland – have enacted national legislation on end-of-life decisions.

Nevertheless, between these countries, a division has been made based on the level of protection of patient autonomy and the role of physicians in end-of-life situations. The result is that all the policies analyzed protect patient autonomy; the Romance-speaking countries differ from the other groups (English- and German-speaking countries) in that the national parliaments of the Romance-speaking countries have also underlined the significance of the role of physicians. In England and Germany, national laws do not rely on physicians' decisions, giving this power to medically neutral

persons. In those countries, this is considered the best way to protect patient autonomy against the interests of physicians, who in the past have been criticized for paternalism. Among the countries analysed in detail, the German parliament has adopted the most liberal approach.

Within the countries surveyed, the Italian situation in end-of-life situations is the most complex because Italy is one of the few Western European countries that lack an *ad hoc* law regulating ADs. Moreover, the Italian bioethical community has adopted controversial positions: from a complete paternalist approach in 1993 to a liberal one in 2014. On the other hand, the medical community has recently adopted a conservative approach in 2014; the previous version of the Italian Code of Medical Ethics – the one of 2006 – was more liberal. In addition, the jurisprudence has filled the gap in legal norms governing advance directives by applying constitutional rights or by offering an extensive interpretation of existing legal rules. The most important case law is that set in *Eluana Engalro*, and the same legal reasoning has recently been adopted by the Italian Council of State in its ruling of 2 September 2014, no. 4460. Since Italy is not part of the common-law system, judges are not obliged to follow the principle of precedent.

In Italy, since the case law set in *Eluana Englaro*, the Italian Parliament has tried to pass legislation on end-of-life decisions. Until now, Bill no. 2350, "*Provisions relating to therapeutic alliance, informed consent and advance directives for treatments*," is the only act that has been debated by Italian deputies and senators. The paternalist approach of taken in this bill has recently been confirmed by one of the latest proposals – Proposal Bill no. 2229, proposed by Ms. Roccella and others on 26 March 2014 – and in Article 38 of the new Italian Code of Medical Ethics of May 2014.

Italy should have a specific law governing end-of-life decisions. The law should take into account the rulings of the Italian Constitutional Court and of Italian judges, who until now have substituted the Italian legislator by rendering individual rulings protecting patient autonomy and the right to self-determination. In addition, the experience of other Western European

countries should be taken into consideration. However, the particularity of Italian medical culture, which underlines the significance of role of the medical staff in end-of-life decisions, should be considered as well.

Until then, Italian judges should protect the patient's autonomy by applying the current laws without conflating the legal figure of a guardian with that of a surrogate: an extended interpretation of Articles 404–413 C.C. in light of the constitutional right to self-determination can be applied. Only in cases where, in the near future, incapacity is almost certain and patients have received detailed information about the medical consequences of their diseases should guardian be appointed – and not only designated – when citizens are fully competent.

Nevertheless, Italian judges should take into account not only the interpretation of constitutional rights, but also documents published by the Italian Bioethical Committee, in addition to reflecting on the suggestions from the main medical organizations, such as SIAARTI and FNOMCeO, and of patient associations. It may be that if the Italian legislator has not regulated end-of-life decisions, the reason for this gap in the law is to avoid ossifying normative rules, subjective values, and ethical principles that in society are flexible and in flux. Thus, as the medical community argues, the Italian parliament does not prefer end-of-life decisions to be resolved simply through legal technicalities and arguments, but is rather looking to take into consideration the role of culture, society, family, and physicians.

The possibility of dialogue with physicians, and therefore a program of a care planning, is aimed at emphasizing the patient-physician trust. In addition, the ability to have the medical and clinical information regarding the progress of the disease highlights patient autonomy. Moreover, since identity and interests are seen as dynamic and continuously shaped by relationships with other people, giving the citizen the right to designate and then appoint his or her legal proxy is more coherent with the new approach to autonomy as a relational principle. Furthermore, this approach reflects the results of the

new European legislative trend towards giving priority to the establishment of private continuing powers of attorney over public measures of protection.

Until now, the proposals for a new bill regarding advance directives comprise three from the Senate and five from the Chamber of Deputies, which are Proposal Bills 5, 13, 443, 1142, 1298, 1432, 2229, and 2264. It should be noted that the Proposal Bills 5 and 1142 are similar. Moreover, the Proposal Bill 2229 adopted the same paternalist and conservative approach as Bill 2350. In addition, Proposal Bill 1432 contains only one article; therefore, it lacks several procedural norms and makes the false assumption that the European Convention on Human Rights and Biomedicine of April 1997 is executive in Italy.

Of all these proposal bills, Proposal Bills 13 and 1298 should be pointed out. Proposal Bill 13 is the only one that also governs advance care planning, which underlines the importance of communication and patient-physician trust. It should be noted that several studies have shown that ADs written within advance care planning are more precise and coherent. Furthermore, the main Italian medical organizations also agree on interpreting ADs as legally binding if they were stated within a care planning program.

However, the confusing definition of surrogates in Article 6, section 1, must be noted: the text maintains the power of a surrogate even when the patient is conscious. By contrast, Proposal Bill 1298 draws a clear distinction between "living will" and "surrogate will" and provides all citizens over 16 years old the ability to write an AD.

Proposal Bill 13 "*Norms on the relationship of care, consent, medical emergency, refusal and interruption of care, advance directives*," proposed by Senators Manconi and Corsini on 15 March 2013, which contains 25 articles, is the best option for regulating ADs. Proposal Bill 13 not only governs informed consent and ADs but also regulates advance care planning. Moreover, ADs are not limited in time; the document does not contemplate the principle of the sanctity of life and it emphasizes the significance of the patient's wellbeing as a subjective view of health by the citizen (Article 2). This proposal bill clearly

states that ANH can be withdrawn (Article 18). Since the classification of ANH is under ongoing discussion in Italy, a clear policy in that regard is necessary. It should be noted that Proposal Bill 13 correctly does not make a distinction between gastrostomy and nasogastric feeding.

Furthermore, in the case of the surrogate's absence, no fixed order has been established. This policy is important because citizens would otherwise lose the incentive to write ADs. Additionally, in cases of disagreement between surrogates and physicians, an impartial authority has been established. It must be noted that this proposal bill not only takes into consideration the impartiality of the public body in resolving these conflicts, but it also considers the problem of the costs of a judicial proceeding. Therefore, a pretrial phase has been established. In this phase, experts appointed by the interested parties are to decide. Only if the conflict remains will a judge's ruling be sought.

Bibliography

A

Alvrecht Gary L. and Patrick J. Devlieger, "The Disability Paradox: High Quality of life against all odds." *Social Science & Medicine* 48, no. 8 (1999): 977-988.

Amato, D. Vincenti. "Il silenzio della legge e il testamento di vita." In *Il testamento biologico: riflessioni di dieci giuristi* edited by Fondazione Veronesi, 177-188. Milano: Giuffré, 2010.

American Dietetic Association. "Ethical and Legal Issues in Nutrition, Hydration, and Feeding." *Journal of the American Dietetic Association* 108, no. 5 (2008): 873–882.

Andorno, Roberto. "An Important Step in the Promotion of Patients' Self-Determination" *European Journal of Health Law* 17, no. 2 (2010): 119-124.

Andorno, Roberto. "The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law." *Journal of International Biotechnology Law* 2, no. 4 (2005): 133-143

Andorno Roberto. "Biomedicine and international human rights law: in search of a global consensus." *Bulletin of the World Health Organization* 80, no. 12 (2002): 959–963.

Ashcroft, Richard. "Death Policy in the United Kingdom." In *End-of-life Decision Making: a cross-National Study*, edited by Robert H. Blank and Janna C. Merrick, 197-218. Cambridge: MIT Press, 2005.

Ashley, Viv. "Philosophical models of personal autonomy (version 5)." University of Essex: Essex Autonomy Project (2013).

Ashwal, Stephen and others. "Medical aspects of the persistent vegetative state." *New England Journal of Medicine* 330, no. 21 (1994): 1499-1508.

A.S.P.E.N. Board of directors. "Guidelines for the Use of Parenteral end Enteral Nutrition in Adult and Pediatric Patients." *JPEN. Journal of parenteral and enteral nutrition* 26, no. 1 (2002): 1SA-138SA.

Assamblee Nationale, *Mission d'e´valuation de la loi n° 2005-370 du 22 avril 2005 relative aux droits des malades et a` la fin de vie*, n° 1287, vol. 2, 2008.

Aoun, Samar M. and others. "The experience of supporting a dying relative: Reflections of caregivers." *Progress in Palliative Care* 13, no. 6 (2005) 319–325.

Atkinson, Atkinson M. *Advance Directives in Mental Health: Theory, Practice and Ethics.* London: Kingsley Publishers, 2007.

B

Baier, Annette C. *Moral Prejudices: Essays on Ethics.* Cambridge: Harvard University Press, 1995.

Baier, Annette. "Responseto Olli Lagerspetz." In *Commonality and Particularity in Ethics,* edited by Alanen, Lilli and others,118-122. New York: St. Martin's Press, 1997.

Baier, Annette. *Postures of the Mind: Essays on Mind and Morals.* Minneapolis: University of Minnesota Press, 1985.

Barni, Mauro and others. "Aspetti Medico - Legali e Riflessi Deontologici del Diritto a Morire." *Rivista Italiana di Medicina Legale* 7, no. 3 (1986): 724 – 734.

Balestra, Luigi. "L'autodeterminazione nel «fine vita»" *Rivista Trimestrale di Diritto e Procedura Civile* 65, no. 4 (2011): 1009-1031.

Balestra, Luigi. "Efficacia del testamento biologico e ruolo del medico", In *Il testamento biologico: riflessioni di dieci giuristi* edited by Fondazione Veronesi, 89-106. Milano: Giuffré, 2010.

Beauchamp, Tom L. and James F. Childress. *Principles of Biomedical Ethics*. New York: Oxford University Press, 1979.

Beauchamp, Tom L. "A Reply to Rachels on Active and Passive Euthanasia." In *Contemporary Issues in Bioethics*, edited by Beauchamp Tom L. and LeRoy Walters, 248-255. Belmont: Wadsworth Publishing Company, 1989.

Berger, Jeffrey T. and Deborah Majerovitz. "Stability of Preferences for treatment among Nursing Home Residents." *The Gerontologist* 38, no. 2 (1998): 217–223.

Benbenishty, Julie and others. "Nurse involvement in end-of-life decision making: the Ethicus Study." *Intensive Care Medicine* 32, no. 1 (2006): 129-132.

Ben-Ishai, Elizabeth. *Fostering Autonomy: A Theory of Citizenship, the State and Social Service Delivery.* University Park, PA: Penn State University Press, 2012.

Berger, Jeffrey T. and Deborah Majerovitz. "Stability of Preferences for treatment among Nursing Home Residents." *The Gerontologist* 38, no. 2 (1998): 217–223.

Bilsen, Johan and others. "Drugs used to alleviate symptoms with life shortening as a possible side effect: end-of-life care in six European countries." *Journal of Pain and Symptom Management* 31, no. 2 (2006): 111–121.

Biggs, Hazel. "I don't want to be a burden! A feminist reflects on women's experiences of death and dying." In *Feminist Perspectives on Health Care Law,* edited by Sheldon Sally, 279–295. London: Cavendish Publishing Ltd., 1998.

Blustein, Jeffrey. "Choosing for others as continuing a life story: The problem of personal identity revisited." *The Journal of Law, Medicine & Ethics* 27, no. 1 (1999): 20-31.

Bonsignore, Alessandro and others. "Le Direttive Anticipate di Trattamento nella Prospettiva del Legislatore ed i riflessi Medico-Legale", *Rivista Italiana di Medicina Legale e del Diritto in Campo Sanitario* 34, no. 4 (2012): 1479 – 1493.

Bonilini, Giovanni. "Le norme applicabili all'amministrazione di sostegno." In *L'amministrazione di sostegno* edited by Bonilini, Giovanni and Augusto Ghizzini, 299-301. Padova: Cedam, 2007.

Boyle, Joseph M. "On Killing and Letting Die." *The New Scholasticism* 51, no. 4 (1977): 433-452.

Bramstedt, Katrina A. "Questioning the decision-making capacity of surrogates." *Internal Medicine Journal* 33, no. 56 (2003): 257–259.

Braun Kathrin. *Menschenwürde und Biomedizin. Zum philosophischen Diskurs der Bioethik*. Frankfurt: Campus, 2000.

Braun, Ursula K. and others. "Reconceptualizing the Experience of Surrogate Decision Making: Reports vs Genuine Decisions." *Annals of Family Medicine* 7, no. 3 (2009): 249-253.

British Medical Association. *Statement on advance directives.* London: BMJ Publishing Group, 2007.

British Medical Assossication. *Advanced Statements about Medical Treatment.* London: BMJ Publishing Group, 2007.

British Medical Association. *Withholding and Withdrawing Life-prolonging Medical Treatment Guidance for decision making*. Oxford: Blackwell Publishing, 2007.

Brock, Dan W. "Medical Decisions at the End of Life." In *A Companion to Bioethics*, edited by Kuhse, Helga and Peter Singer, 263-273. Oxford: Wiley-Blackwell, 2009.

Brody, Howard. *Stories of Sickness.* Oxford: Oxford University Press, 2003.

Broom, Alex and Emma Kirby "The end of life and the family: hospice patients' views on dying as relational."*Sociology of Health and Illness* 35, no. 4 (2013): 499-513.

Brugiavini Agar and Tullio Jappelli, *Verso un nuovo sistema di architettura sociale per la famiglia: rischi economici e domanda di assicurazione*. Bologna: il Mulino, 2010.

Buchanan, Allen and Dan W. Brock. *Deciding for Others: The Ethics of Surrogate Decision Making*. Cambridge: Cambridge University Press, 1990.

Buffone, Giuseppe. "L'istituto dell'amministrazione di sostegno." *Giurisprudenza di Merito* 43, no. 11 (2013): 2376-2382.

Budroni, Helmut. "The family as proxy." *Pflege Zeit* 67, no. 10 (2014): 600-603.

Buiting, Hilde M. and others. "Forgoing artificial nutrition or hydration in patients nearing death in six European countries." *Journal of Pain and Symptom Management* 34, no. 3 (2007): 305-314.

Bundesärztekammer, Zentrale Ethikkommission bei der Bundesärztekammer. "Empfehlungen der Bundesärztekammer und der Zentralen Ethikkommission bei der Bundesärztekammer zum Umgang mit Vorsorgevollmacht und Patientenverf ügung in der ärztlichen Praxis." http://www.bundesaerztekammer.de/downloads/Empfehlungen_BAeKZEKO_Vorsorgevollmacht_Patientenverfuegung_19082013l.pdf.

Bundesministerium der Justiz. "Verfahren nach Betreuungsgesetz 1992–2009." http://www.bmj.de/SharedDocs/Downloads/DE/pdfs/Betreuungsgesetz_Verfahren.html).

Busnelli, Francesco D. "Problemi giuridici di fine vita tra natura e artificio" *Rivista di Diritto Civile* 57, no. 2 (2011): 153-172.

Bülow, Hans H. and others. "Are religion and religiosity important to end-of-life decisions and patient autonomy in the ICU? The Ethicatt study." *Intensive Care Medicine* 38, no.7 (2012): 1126–1133.

C

Canestrari, Stefano. "Le diverse tipologie di eutanasia: una legislazione possibile." *Rivista Italiana di Medicina Legale* 25, no. 5 (2003): 751 - 775.

Carmel, Sara and Elizabeth J. Mutran. "Stability of Elderly persons' expressed preferences regarding the use of Life-Sustaining Treatments." *Social Science & Medicine* 49, no. 3 (1999): 303-311.

Carrion, Iraida V. and others. "Advance care planning among Colombian, Mexican, and Puerto Rican women with a cancer diagnosis." *Supportive Care in Cancer : Official Journal of the Multinational Association of Supportive Care in Cancer* 21, no. 5 (2013): 1233-1239.

Catania, Chiara and others. "Opinions concerning Euthanasia, Life-Sustaining Treatment and Acceleration of Death: results of an Italian Association of Medical Oncology (AIOM) survey." *Annals of Oncology : Official Journal of the European Society for Medical Oncology / ESMO* 19(11) (2008) 1947–1954.

Campbell, Margaret L. *Case Studies in Palliative and End-of-life Care*. Detroit: John Wiley & Sons, 2012.

Childress James F. "Love and Justice in Christian Biomedical Ethics." *Philosophy and Medicine* 20, (1985): 225-243.

Code Lorraine. *What Can She Know?: Feminist Theory and the Construction of Knowledge.* Ithaca: Cornell University Press, 1991.

Cohen, Joachim and others. "Influence of physicians' life stances on attitudes to end-of-life decisions and actual end-of-life decision-making in six countries." *Journal of Medical Ethics* 34, no.4 (2008): 247-253.

Corda, Ilara. *Amministrazione di sostegno, interdizione e inabilitazione. Questioni processuali.* Milano: Giuffre, 2010.

Cohen-Mansfield, Jiska and others. "The decision to execute a durable power of attorney for health care and preferences regarding the utilization of life-sustaining treatments in nursing home residents." *Archives of Internal Medicine* 151, no. 2 (1991): 289-294.

Corrigan, Patrick. "How Stigma Interferes with Mental Health Care." *American Psychologist* 59, (2004): 614–625.

Costantini, Massimo and others. "Cancer trajectories at the end of life: is there an effect of age and gender?" *BMC Cancer* 2, no. 8 (2008): 127.

Costantini, Massimo and others. "Diagnosis and prognosis disclosure among cancer patients. Results from an Italian mortality follow-back survey." *Annals of Oncology: Official Journal of the European Society for Medical Oncology / ESMO* 17, no. 5 (2006): 853–859.

Cranford, Ronald E. and David R. Smith. "Consciousness: The most critical moral (constitutional) standard for human personhood." *American Journal of Law and Medicine* 13, no. 2-3 (1987): 233-248.

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

Council of Europe, Explanatory Report Recommendation CM/Rec (2009) 11.

Council of Europe, Explanatory Report of the Convention on Human Rights and Biomedicine No. 164/1996

D

D'Avack, Lorenzo. "Il disegno di legge sul consenso informato all'atto medico e sulle dichiarazioni anticipate di trattamento, approvato al senato, riduce l'autodeterminazione del paziente e presenta dubbi di costituzionalità." *Il Diritto di Famiglia e delle Persone* 38, no. 3 (2009): 1281-1299.

Daveson, Barbara A. and others. "To be involved or not to be involved: a survey of public preferences for self-involvement in decision-making involving mental capacity (competency) within Europe." *Palliative Medicine* 27, no. 5 (2013): 418-427.

De Boer Marike E. and others. "Advance Directives in Dementia: Issues of Validity and Effectiveness." *International Psychogeriatrics* 22, no. 2 (2010): 201-208.

De Luca, Federica and others. "Il disegno di legge circa le disposizioni anticipate di trattamento (alla luce delle modifiche del testo emanato dalla camera il 12 luglio 2011)." *Rivista Italiana di Medicina Legale e del Diritto in Campo Sanitario* 33, no. 3 (2012): 1062-1077.

Degner Lesley F. and others. "The Control Preferences Scale." *The Canadian Journal of Nursing Research = Revue Canadienne de Recherche en Sciences Infirmières* 29, no. 3 (1997): 21–43.

Department of Health "End of life care strategy: promoting high quality care for all adults at the end of life". https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/136431/End_of_life_strategy.pdf

Deutsch, Erwin and Andreas Spickhoff. *Medizinrecht: Arztrecht, Arzneimittelrecht, Medizinprodukterecht und Transfusionsrecht*. Berlin: Springer-Verlag, 2008.

Devettere, Raymond J. *Practical decision making in health care ethics: cases and concepts*. Washington: Georgetown University Press, 2010.

Dickenson, Donna L. "Cross-cultural issues in European bioethics." *Bioethics* 13, no. 3-4 (1999): 249–255.

Ditto, Peter H. and others "Stability of older adults' preferences for life-sustaining medical treatment." *Health psychology : official journal of the Division of Health Psychology, American Psychological Association* 22, no. 6 (2003): 605–615.

Druss Benjamin G. and Steven C. Marcus. "Growth and decentralization of the medical literature: implications for evidence-based medicine." *Journal of the Medical Library Association : JMLA* 93, no. 4 (2005): 499-501.

Dupont, Bernard M. "Refuse a 'Vincent Humbert law'." *Médecine Palliative* 4, no. 6 (2005): 309-311.

Dupont, Bernard M. "Refuse a 'Vincent Humbert law'." *Médecine Palliative* 4, no. 6 (2005): 309-311.

Dworkin, Ronald. "Autonomy and the Demented self." *Milbank Quartely* 64, no. 2 (1986): 4-16.

E

Entwistle, Vikki and others. "Supporting Patient Autonomy: The Importance of Clinician-patient Relationships." *Journal of General Internal Medicine* 25 (2010): 741–745.

Epstein, Ronald M. "Whole mind and shared mind in clinical decision-making." *Patient Education and Consulting* 90, no. 2 (2013):200-206.

Erin, Charles A. and John Harris. "Living Wills: Anticipatory Decisions and Advance Directives." *Reviews in Clinical Gerontology* 4, no. 3 (1994): 269 – 275.

Escher, Monica and others. "Impact of advance directives and a health care proxy on doctors' decisions: a randomized trial." *Journal of Pain and Symptom Management* 47, no. 1 (2014): 1-11.

Evans, Natalie and others. "A critical review of advance directives in Germany: attitudes, use and healthcare professionals' compliance." *Patient Education and Counseling* 87, no.3 (2012): 277-288.

Eurostat. "Mortality and life expectancy statistics." http://ec.europa.eu/eurostat/statistics-explained/index.php/Mortality_and_life_expectancy_statistics

European Commission "Long-term care: need, use and expenditure in the EU-27." http://ec.europa.eu/economy_finance/publications/economic_paper/2012/pdf/ecp469_en.pdf

F

Fagerlin, Angela and others. "The use of advance directives in end-of-life decision making." *American Behavioural Scientist* 46, no. 2 (2002) 268–283.

Fagerlin, Angela and Schneider, Carl E. "Enough. The Failure of the Living Will." *The Hastings Center Report* 34, no. 2 (2004): 30–42.

Fan, Ruiping. "Self-Determination vs. family-determination: two incommensurable principles of autonomy." *Bioethics* 11, no. 3-4 (1997): 309-322.

Faunce, Thomas A. "Will international human rights subsume medical ethics? Intersections in the UNESCO Universal Bioethics Declaration." *Joulnal of Medical Ethics* 31, no. 3 (2005): 173-178.

Forbes Gorgon and others. "Relationships between individualism-collectivism, gender, and direct or indirect aggression: a study in China, Poland, and the US." *Aggressive Behaviour* 35, no.1 (2009): 24-30.

Frankfurt, Harry. "Freedom of the Will and the Concept of the Person". In *The Inner Citadel: Essays on Individual Autonomy*, edited by Christman, John Philip, 63–76. New York: Oxford University Press, 1989.

French National Medical Council. Avis sur Fin de vie, arrêt de vie, euthanasie. http://www.ccne-ethique.fr/sites/default/files/publications/avis063.pdf

Frolik, Lawrence A. "Is a Guardian the Alter Ego of the Ward?" *Stetson Law Review* 37, no. 53 (2007-2008): 53-86.

G

Gabl, Christoph and Ralf J. Jox. "Paternalism and autonomy--no contradiction." *Wiener medizinische Wochenschrift* 158, no. 23-24 (2007): 642-649.

García Ortega, Cesáreo and others. **"**Patient autonomy and information and clinical documentation-related rights within the context of Spanish Law 41/2002" *Revista Española de Salud Pública* 78, no. 4 (2004): 469-479.

Gardiner Clare and others. “Exploring the transition from curative care to palliative care: a systematic review of the literature.” *British Medical Journal of Supportive & Palliative Care* 20, no. 1, (2011): 56–63.

General Medical Council. *Seeking Patients’ Consent: the Ethical Considerations.* London, 1998.

General Medical Council. *Consent: Patients and doctors making decisions together*. London, 2008.

General Medical Council. *Treatment and care towards the end of life: Good practices in decision making.* London, 2010.

Giger, Joyce N. and others. “Multi-cultural and multi-ethnic considerations and advance directives: Developing cultural competency.” *Journal of Cultural Diversity* 13, no. 1 (2006): 3–9.

Giunta, Fausto. “Diritto di Morire e Diritto Penale. I termini di una Relazione Problematica.”, *Rivista Italiana di Diritto e Procedura Penale* 50, no. 1 (1997): 74 – 125.

Goffin, Tom and others. “Why eight EU Member States signed, but not yet ratified the Convention for Human Rights and Biomedicine.” *Health Policy* 86, no. 2-3 (2008): 222-233.

Goldberg, Jaime H. “Family Carers in Palliative Care: A Guide for Health and Social Care Professionals.” *Journal of Palliative Medicine* 13, no. 3 (2010): 339–340.

Gomes Barbara and others. Local Preferences and Place of Death in Regions within England 2010. National end of life care Intelligence Network. London: Cicely Saunders Institute, 2011.

Gorgoni, Antonio. “Amministratore di sostegno e trattamenti sanitari.” *Europa e Diritto Privato* 14, no. 2 (2012): 547-616.

Grande, Giuseppe and others. “Supporting lay carers in end of life care: current gaps and future priorities” *Palliative Medicine* 23, no. 4 (2009): 339–344.

Griffith, John and others. *Euthanasia and the law in Europe*. Oxford: Hart Publishing, 2008.

Guarnieri, Attilio. “Profili Giuridici della Fine della Vita Umane.” *Responsabilità Civile e Previdenza* 34, no. 9 (2009): 1707 – 1726.

H

Hales, Sarah and others. “The quality of dying and death.” *Archives of Internal Medicine* 168, no.9 (2008): 912–918.

Harding, Richard and Irene J. Higginson. “What is the best way to help caregivers in cancer and palliative care?.” *Palliative Medicine* 17, no. 1 (2003): 63–74.

Hawkins, Nikki A. and others. "Micromanaging death: process preferences, values, and goals in end-of-life medical decision making." *GERONTOLOGIST* 45, no. 1 (2005): 107-117.

Holley, Jean L. "Palliative care in end-stage renal disease: focus on advance care planning, hospice referral, and bereavement." *Seminars in Dialysis* 18, no. 2 (2005): 154–156.

Horn, Ruth "'I don't need my patients' opinion to withdraw treatment'': patient preferences at the end-of-life and physician attitudes towards advance directives in England and France'." *Medicine, Health care, and Philosophy* 17, no. 3 (2014): 425-435.

Horn, Ruth. "Euthanasia and end-of-life practices in France and Germany. A comparative study." *Medicine, Health Care and Philosophy* 16, no. 2 (2013): 197-209.

Horn, Ruth J. "Advance Directives in English and French Law: Different Concepts, Different Values, Different Societies." *Health Care Analysis : HCA : Journal of Health Philosophy and Policy* 22, no. 1 (2014): 59–72.

Hoppe, Nils and José Miola. *Medical law and medical ethics*. Cambridge: Cambridge University Press, 2014.

Howarth, Glennys. *Death & Dying: A Sociological Introduction.* Cambridge: Polity Press, 2007.

Hunt, Matthew R. and Carolyn Ells. "Partners towards autonomy: risky choices and relational autonomy in rehabilitation care" *Disability and Rehabilitation* 33, no. 1 (2011) 961-967.

Howard, Robinson. "Dualism." In *The Stanford Encyclopedia of Philosophy,* edited by Edward N. Zalta, 2003. http://plato.stanford.edu/entries/dualism/

Hunt, Sonja M. and others. *Measuring Health Status*. London: Croom Helm, 1986.

Hudson, Peter and Sheila Payne. "Family caregivers and palliative care; current status and agenda for the future." *Journal of Palliative Medicine* 14, no. 7 (2011): 864–869.

I

Iadecola, Gianfranco. "Note critiche in tema di "testamento biologico"." *Rivista Italiana di Medicina Legale* 24, no. 3-4 (2003): 473 – 483.

Iasevoli, Mario "*Decisioni ed Opinioni nel Fine Vita: Confronto tra i diversi Professionisti coinvolti nell'Assistenza al Paziente. Lo Studio Pilota E.L.D.Y.*" (PhD Thesis in Scienza Geriatriche ed Ematologiche in Università degli Studi di Padova, Scuola di dottorato di ricerca in science mediche, cliniche e sperimentali) 2013.

Infantino, Daniela. "Direttive anticipate a amministrazione di sostegno." *La Nuova Giurisprudenza Civile Commentata* 27, no. 6 (2011): 487-492.

ISTAT. "Separazioni e divorzi in Italia" http://www.istat.it/it/archivio/126552

Italian National Bioethics Committee, *Dementia and Alzheimer: ethical consideration.* Roma, 2014.

Italian National Bioethics Committee, *Consciousness objection and bioethics.* Roma, 2012.

Italian National Bioethics Committee, *Conscious withholding or withdrawing medical treatments in the patient-physician relationship*. Roma, 2008.

Italian National Bioethics Committee, *Alimentation and the nutrition and hydration for patients in a persistent vegetative state.* Roma, 2005.

Italian National Bioethics Committee, *Advance directives.* Roma, 2003.

Italian National Bioethics Committee, *Bioethical issues regarding end-of-life.* Roma, 1995.

Italian Society for Anastasia Analgesia Resuscitation and Intensive Care. *Disposizioni in materia di alleanza terapeutica, consenso informato e dichiarazioni anticipate di trattamento (DAT),* Memoria audizione Senato della Repubblica Commissione Igiene e Sanità – 29 settembre 2011.

Italian Society of Anaesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) *"End-of-life, vegetative state, nutrition and hydration"*. 2009.

Italian Society of Anaesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) *"End-of-life and the intensivist: SIAARTI recommendations on the management of the dying patient".* 2006.

Italian Society of Anaesthesia Analgesia Resuscitation and Intensive Care (SIAARTI) *"Grandi insufficienze d'organo "end stage": cure intensive o cure palliative? "Documento condiviso" per una pianificazione delle scelte di cura"*. 2013.

Italian Society of Parenteral and enteral nutrition. *Precisazioni in Merito alle Implicazioni Bioetiche della Nutrizione Artificiale.* http://www.sicp.it/sites/default/files/Precisazioni.pdf

J

James, Rachels. "Active and passive euthanasia." *The New England journal of medicine* 292, no. 2 (1975): 78-80.

Jasmeet, Soar and others. "Emergency treatment of anaphylactic reactions Guidelines for healthcare providers." *RESUSCITATION* 77, no. 2 (2008): 157-169.

Jelllinek, Georg. *Die sozialethische Bedeutung von Recht, Unrecht und Strafe.* Berlin: O. Häring, 1908.

Joint Committee on the Draft Mental Incapacity Bill. *Draft Mental Incapacity Bill* (1st Report, Session 2002-03, HL 189-I), http://www.publications.parliament.uk/pa/jt/jtdmi.htm.

Jox, Ralf J. and others. "Substitute decision making in medicine: comparative analysis of the ethico-legal discourse in England and Germany." *Medicine, Health care, and Philosophy* 11, no. 2 (2008): 153-163.

K

Kapp, Marshall B. "Commentary, "Anxieties as a Legal Impediment to the Doctor-Proxy Relationship." *Journal of Law, Medicine & Ethics* 27, no. 1 (1999): 69-73.

Karasz Alison, and others. "The rational choice model in family decision making at the end of life." *The Journal of Clinical Ethics.* 21, no. 3 (2010): 189-200.

Karel, Jennifer and others. "Assessment of Capacity to consent to Treatment: Challenges, the 'ACCT' Approach, Future Directions." *Clinical Gerontologist* 31, no. 3 (2007): 37–66.

Karen, Steinhauser E. and others. "In Search of a Good Death: Observations of Patients, Families, and Providers" *Annals Internal Medicine* 132, no. 10 (2000): 825-832.

Kellehear, Allan. "Dying as a social relationship: a sociological review of debates on the determination of death." *Social Science and Medicine* 66, no. 7 (2008): 1533–1544.

Kelly, David F. *Medical Care at the End of Life A Catholic Perspective*. Washington: Georgetown University Press, 2006.

Kelk, Constantijn. "Previously expressed wishes relating to end of life decisions." In: In *Health law, Human Rights and the Biomedicine Conention: essays in honour of Henrietee Roscam Abbing*, edited by Gevers Sjef K.L. and others, 131 - 145. Leiden: David Adams, 2005.

Kemp, Peter and others. *Bioethics and Biolaw*. Copenhagen: Rhodos International Publishers, 2000.

Kemp, Peter and Jacob Dahl Rendtorff. "The Barcelona Declaration: Towards an integrated approach to basic ethical principles." *Synthesis Philosophica* 46, no. 2 (2008): 239-251.

Keown, John "Restoring Moral and Intellectual Shape to the Law after *Bland.*" *The Law Quarterly Review* 113, (1997): 481-503.

Kish Wallace, S., and others. "Influence of an Advance Directive on the Initiation of Life Support Technology in Critically Ill Cancer Patients." *Critical Care Medicine* 29, no. 12 (2001): 2294–2298.

Kim, Scott Y. H. and others. "Surrogate consent for dementia research: a national survey of older Americans." *Neurology* 72, no. 2 (2009): 149–155.

King, Deborah A. and Timothy Quill. "Working with families in palliative care: One size does not fit all." *Journal of Palliative Medicine* 9, no. 3 (2006): 704–715.

Knoppers, Bartha M. *Human Dignity and Genetic Heritage: A Study Paper*. Ottawa: Law Reform Commission of Canada, 1991.

Knowles, Lori P. "The lingua franca of human rights and the rise of a global bioethics." *Cambridge Quarterly of Healthcare Ethics : CQ : the International Journal of Healthcare Ethics Committees* 10, no. 3 (2001): 253-63.

Kuhse Helga. "Why Killing is not Always Worse – and Sometimes Better – Than Letting Die." *Cambridge Quarterly of Healthcare Ethics* 7, no. 4 (1998): 371-374.

L

Lacroix Eve M. and Robert Mehnert. "The US National Library of Medicine in the 21st century: expanding collections, non traditional formats, new audiences." *Health Information and Libraries Journal* 19, no. 3 (2002): 126–132.

Lagerspetz, 0lli "The Notion of Trust in Philosophical Psychology." In *Commonality and Particularity in Ethics,* edited by Alanen, Lilli and others, 95-117. New York: St. Martin's Press, 1997.

Lang, Frieder R. and Gert G. Wagner. "Patient living wills in Germany: conditions for their increase and reasons for refusal." *Deutsche medizinische Wochenschrift* 132, no. 48 (2007):

2558–2562.

Lang, Frieder R. and others. Desired lifetime and end-of-life desires across adulthood from 20 to 90: a dual-source information model." *The Journals of Gerontology. Series B, Psychological Sciences and Social Sciences* 62, no. 5 (2007): 268–278.

Lavoie, Mireille and others. "The autonomy experience of patients in palliative care." *Journal of Hospice & Palliative Nursing* 13, no. 1 (2011): 47–53.

Lawrence, Ryan E., and Daniel J. Brauner, "Deciding for others: limitations of advance directives, substituted judgment, and best interest." *Virtual Mentor VM* 11, no. 8 (2009): 571-581.

Lecaldano, Eugenio. *Bioetica. Le scelte morali.* Bari-Roma: Laterza, 2005.

Leider John P., and others. "Public health spending in 2008: on the challenge of integrating PHSSR data sets and the need for harmonization." *Journal of Public Health Management and Practice : JPHMP* 18, no. 4 (2012): 355-363.

Letsas, George. "Strasbourg's Interpretive Ethic: Lessons for the International Lawyer." *European Journal of International Law* 21, no. 3 (2010): 509-541.

Lewis, Megan A. and Karen S. Rook "Social Control in Personal Relationships: Impact on Health Behaviors and Psychological Distress." *Health Psychology* 18, no. 1 (1999): 63–71.

Lingler, Jennifer H. and others. "Temporal stability of receptiveness to clinical research on Alzheimer disease in Alzheimer disease." *Alzheimer Disease and Associated Disorders* 24 (2010): S30-4.

Locke, John. *The two treatises of government*. London: Everyman Paperback, 1993. [original work published 1690].

Löfmark, Rurik and others. "Physicians' experiences with end-of-life decision-making: survey in 6 European countries and Australia." *BMC Medicine* 12, no. 6 (2008): 4.

M

Macintyre, Alasdair. *After Virtue: A Study in Moral Theory.* Notre Dame: University of Notre Dame Press, 2007.

Mackenzie, Catriona and Natalie Stoljar. *Relational Autonomy: Feminist Perspective on Autonomy, Agency, and the Social Self.* New York: Oxford University Press, 2000.

Manson Kenyon and Graeme Laurie. *Mason and McCall Smith's Law and Medical Ethics.* Oxford: Oxford University Press, 2011.

Maguire Daniel C. *Death by Choice.* Garden City: Doubleday & Company, Inc., 1984.

Maltese, Domenico. "Il Falso Problema della Nutrizione Artificiale." *Il Foro italiano* 134, no.4 (2009): 987 – 989.

Marion, Danis and others. "Stability of Choices about Life-Sustaining Treatments." *Annals of Internal Medicine* 120, no. 7 (1994): 567-573.

Masoni, Roberto. "I testimoni di Geova tra Legittimità, Merito ed Amministrazione di Sostegno." *Diritto Famiglia e delle Persone* 38, no. 1 (2009): 58 – 73.

Menaca, Arantza and others. "End-of-life Care across Southern Europe: a Critical Review of Cultural Similarities and Differences between Italy, Spain and Portugal." *Critical Reviews in Oncology/Hematology* 82, no. 3 (2012): 387-401.

Miccinesi, Guido and others. "Continuous Deep Sedation: Physicians' Experiences in six European countrie." *Journal of Pain and Symptom Management* 31, no. 2 (2006): 122–129.

Michalowski, Sabine. "Advance Refusals of Life-sustaining Medical Treatment: the Relativity of an Absolute Right." *Modern Law Review* 68, no. 6 (2005): 958–982.

Mill, John S. *On liberty*. New York: Simon & Brown, 2012. [original work published 1865].

Molaschi, Viviana. "Withdrawal of Artificial Hydration and Nutrition from a Patient in a Permanent Vegetative State in Italy: some considerations on the Englaro case." *Italan Journal of Public Law* 5, no. 2 (2012): 122-158.

Mollaret Pierre and Maurice Goulon "Le coma dépassé." *Revue Neurologique* 101, no. 1 (1959): 3-15.

N

Navarro-Michel, Monica. "Advance Directives: the Spanish Perspective." *Medical Law Review* 13, no. 2 (2005): 137-169.

Nebel, Sara. "Facing death together: Exploring the conceptualizations of hospice patients and family as a single unit of care." *Journal of Hospice and Palliative Nursing* 13, no. 6 (2011): 419–425.

Neitzke, Gerald. "Umgang mit Patientenverfügungen in der Praxis." *Public Health Forum* 21, no. 3 (2013).

Neitzke, Gerald and others. "Göttinger Thesen zur gesetzlichen Regelung des Umgangs mit Patientenverfügung und Vorsorgevollmacht." *Ethik in der Medizin* 18, no. 2 (2006): 192–194.

Neri, Demetrio. "Autonomia e Dignità della Persona alla Fine della Vita. Chi decide?" In *Autonomia e limite. Siamo liberi di scegliere*?, edited by Commissione Bioetica della Tavola Valdese - AA.VV. - Luca Savarino (Piacenza: Vicolo del Pavone 2010).

New York State Task Force on Life and the Law, *Life- Sustaining Treatment: Making Decisions and Appointing a Health Care Agent.* Albany: New York State Task Force on Life and the Law, 1987.

Nussbaum, Martha C. *Women and Human Development: The Capabilities Approach.* Cambridge: Cambridge University Press, 2000.

O

Oddie Graham. "Killing and letting-die: Bare differences and clear differences." *Philosophical Studies* 88, no.3 (1997): 267-287.

Olick, Robert S. "On the Scope and Limits of Advance Directives and Prospective Autonomy." In *Advance Directives*, edited by Peter Lack and others, 53-72. New York: Springer, 2014.

Oshana, Marina. *Personal autonomy in society.* Aldershot: Ashgate Press, 2006.

Owens, John. "Creating an Impersonal NHS? Personalization, Choice and the Erosion of Intimacy." *Health Expectations* 18, no. 1 (2015): 22-31

Owens, John and Alan Cribb, "Beyond Choice and Individualism: Understanding Autonomy for Public Health Ethics." *Public Health Ethics* 6, no. 3 (2013): 262-271.

P

Parfit, Derek. *Reasons and Persons*. Oxford: Oxford University Press, 1984.

Pasquino, Teresa. *Autodeterminazione e dignità della morte*. Padova: Cedam, 2009.

Pecanac, Kristen E. and others "Respecting Choices and advance directives in a diverse community." *Journal of Palliative Medicine* 17, no. 3 (2014): 282-287.

Pennec, Sophie and others. "End-of-life medical decisions in France: a death certificate follow-up survey 5 years after the 2005 act of parliament on patients' rights and end of life." *BMC Palliative Care* 3, no. 11 (2012): 25.

Pereira, André D. "Living will and health care proxy–the Portuguese legal situation" *Medicine and Law* 32, no. 4 (2013): 497–502.

Pereira, Ray. "Human handicap and self-determination: compassion and insensibility in the Vincent Humbert case." *História, Ciências, Saúde-Manguinhos* 14, no.1 (2007): 119-134.

Perrett, Royw W. "Killing, letting die and the bare difference argument." *Bioethics* 10, no. 2 (1996): 131-139.

Pope Thaddeus. "The best interest standard: both guide and limit to medical decision making on behalf of incapacitated patients." *The Journal of Clinical Ethics* 22, no. 2 (2011): 134-138.

Pope, Thaddeus M. "Legal Fundamentals of Surrogate Decision Making", *Chest* 141, no. 4 (2012): 1074–1081.

Powell, Tia. "Extubating Mrs. K: Psychological Aspects of Surrogate Decision Making." *Journal of Law, Medicine* & *Ethics,* 27, no. 1 (1999): 81-86.

Prendergast, Thomas J. "Advance Care Planning: Pitfalls, Progress, Promise." *Critical Care Medicine* 29, no. 2 Suppl (2001): N34–N39.

Prah Ruger, Jennifer. *Health and Social Justice.* Oxford: Oxford University Press, 2010.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Deciding to Forego Life-Sustaining Treatment.* Washington: U.S. Government Printing Office, 1983.

Probst, Martin and Bernhard Knittel. "Gesetzliche Vertretung durch Angehörige – Alternative zur Betreuung?" *Zeitschrift für Rechtspolitik* 34, no. 2 (2001): 55-60.

Puchalski, Christina M. and others. "Patients who want their family and physician to make resuscitation decisions for them: observations from

SUPPORT and HELP. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment. Hospitalized Elderly Longitudinal Project." *Journal of the American Geriatrics Society* 45, no. 5 Suppl (2000): S84-90.

R

Rabkin, Mitchell T. and others. "Orders not to resuscitate." *New England Journal of Medicine* 295, no.7 (1976): 364-366.

Rachels, James. "Active and passive euthanasia." *The New England Journal of Medicine* 292, no. 2, (1975):78-80.

Rendtorff, Jacob Dahl. "Basic ethical principles in European bioethics and biolaw: autonomy, dignity, integrity and vulnerability–towards a foundation of bioethics and biolaw." *Medicine, Health Care and Philosophy* 5, no. 3 (2002): 235-244.

Ricoeur, Paul. *Oneself as Another.* Chicago: University of Chicago Press, 1995.

Richardson, Henry S. "Specifying, balancing, and interpreting bioethical principles." In *Belmont Revisited: Ethical Principles for Research with Human Subjects*, edited by James F. Childress and others, 205–227. Washington, DC: Georgetown University Press, 2005.

Rini, Christine and others. "Interpersonal Influences on Patient's Surgical Decision Making: The Role of Close Others." *Journal of Behavioral Medicine* 34, no. 5 (2011): 396–407.

Robin L. Fainsinger, and others. "The cultural differences in perceived value of disclosure and cognition: Spain and Canada." *Journal of Palliative Care* 19, no. 1 (2003): 43–48.

Rodotà, Stefano. *Perché laico*. Roma-Bari: Laterza, 2009.

Rodríguez-Arias, David and others. "Advance directives and the family: French and American perspectives." *Clinical Ethics* 2, no. 3 (2007): 139–145.

Roger, Claire and others. "Practices of end-of-life decisions in 66 southern French ICUs 4 years after an official legal framework: A 1-day audit" *Anaesthesia, Critical Care and Pain Medicine* 34, no. 2 (2015): 73-77.

Rossi, Paolo G. and others. "Dying of cancer in Italy: impact on family and caregiver. The Italian Survey of Dying of Cancer." *Journal of Epidemiology and Community Health* 61, no. 6 (2007): 547-554.

Rousseau, Jean J. *Du contrat social*. Paris, Flammarion, 2001. [original work published 1762].

Rubin, Allie N. and Katrina A Bramstedt. "Examining the root cause of surrogate conflicts in the intensive care unit and general wards." *Monash Bioethics Review* 29, no. 1 (2010): 06.1-11.

S

Sabatino, Charls P. "The Legal and Functional Status of the Medical Proxy: Suggestions for Statutory Reform." *Journal of Law, Medicine & Ethics* 27, no. 1 (1999): 52-68.

Sahm, Stephan and others. "Attitudes Towards and Barriers to Writing Advance Directives Amongst Cancer Patients, Healthy Controls, and Medical Staff." *Journal of Medical Ethics* 31, no. 8 (2005): 437–440.

Salvatore, Barbara. "Principio di autodeterminazione e decisioni di fine vita" *Rivista di Diritto Privato* 18, no. 1 (2013): 107-133.

Schicktanz, Silke. "Interpreting advance directives: ethical considerations of the interplay between personal and cultural identity." *Health Care Analysis : HCA : Journal of Health Philosophy and Policy* 17, no. 2 (2009): 158-71.

Schicktanz, Silke and others. "The cultural context of patient's autonomy and doctor's duty: passive euthanasia and advance directives in Germany and Israel." *Medicine, Health Care, and Philosophy* 13, no. 4 (2010): 363-369.

Shickle, Derren. "The Mental Capacity Act 2005." *Clinical Medicine* 6, no. 2 (2006): 169–173.

Schroder, Christina and others. "Representative survey of German people concerning enlightenment and patient directive in a case of terminal illness." *Psychotherapie, Psychosomatik, medizinische Psychologie* 52, no.5 (2002): 236–243.

Seale, Clive. *Constructing Death: The Sociology of Dying and Bereavement.* Cambridge: Cambridge University Press, 1998.

Sehgal, Ashwini and others. "How strictly do dialysis patients want their advance directives followed?" *Journal of the American Geriatrics Society* 267, no. 1 (1992): 59-63.

Sen, Amartya. "Well-Being, Agency and Freedom: The Dewey Lectures 1984." *Journal of Philosophy* 82, no. 4 (1985): 169–221.

Sesta, Michele. "Riflessioni sul testamento biologico." *Famiglia e Diritto* 15, no. 4 (2008): 407-411.

Seymour Jane and others. "Planning for end of life: the views of older people about advance care statements." *Social Science & Medicine* 59, no. 1 (2004): 57–68.

Shakespeare, Tom. *Disability research today: International perspectives.* London and New York: Routledge, 2015.

Shumaker, Sally A. and Richard A. Berzon. *The International Assessment of Health-related Quality of Life: Theory, Translation, Measurement and Analysis*. Oxford: Rapid Communications, 1995.

Siegel, Mark D. and others. "Psychiatric Illness in the next of Kin of Patients who die in the Intensive Care Unit." *Critical Care Medicine* 36, no. 6 (2008): 1722-1728.

Skilbeck Julie K. and Sheila Payne. "End of life care: a discursive analysis of specialist palliative care nursing Periodical." *Journal of Advanced Nursing* 51, no. 4 (2005): 325–334.

Sokalska Maria E. "Implementation of the Convention in Central Europe: the Case of Poland." In *Health law, Human Rights and the Biomedicine Conention: essays in honour of Henrietee Roscam Abbing*, edited by Gevers Sjef K.L. and others, 255-268. Leiden: David Adams, 2005.

Spoto, Giuseppe. "Questione di Fine Vita tra modelli adottati in Europa, negli Stati Uniti e Proposte Interne." *Europa e diritto privato* 4 (2011) 1175 - 1196.

Sprung, Charles L. and others. "The importance of religious affiliation and culture on end-of-life decisions in European intensive care units." *Intensive Care Medicine* 33, no.10 (2007): 1732-1739.

Sprung, Charles L. and others. "Attitudes of European physicians, nurses, patients, and families regarding end-of-life decisions: the Ethicatt study." *Intensive Care Medicine* 33, no.1 (2007): 104–110.

Sprung, Charles L. and others. "Relieving suffering or intentionally hastening death: where do you draw the line?" *Critical Care Medicine* 36, no.1 (2008): 8-13.

Sprung, Charles L. and others. "Reasons, considerations, difficulties and documentation of end-of-life decisions in European intensive care units: the Ethicus Study." *Intensive Care Medicine* 24, no.2 (2008): 271-277.

Steinbock, Bonnie *The Oxford handbook of Bioethics.* Oxford: Oxford University Press, 2009.

Spinsanti, Sandro. "Obtaining consent from the family: a horizon for clinical ethics." *The Journal of Clinical Ethics* 3, no. 3 (1992): 188–192.

Steering Committee on Bioethics, (prepared by Hacpille Lucie) "Medical decisions in end-of- life situations and the ethical implications of the available options" http://www.coe.int/t/dg3/healthbioethic/Activities/09_End%20of%20Life/CDBI_2008_30%20Hacpille%20e.pdf

Steinbock, Bonnie *The Oxford handbook of Bioethics.* Oxford: Oxford University Press, 2009.

Swetz Keith M. and others. "Advance directives, advance care planning, and shared decision making: promoting synergy over exclusivity in contemporary context." *Journal of Pain and Symptom Manage* 47, no. 3 (2014): e1-3.

T

Technical and Scientific Commisison on "*Vegetative state and minimum conscious state*" established with the Ministerial Decree of 12 September

2005
http://www.aduc.it/generale/files/allegati/cure_stato_vegetativo.pdf

Teno, Joan M and others. "Do advance directives provide instructions that direct care? SUPPORT Investigators. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment." *Journal of the American Geriatrics Society* 45, no. 4 (1997): 508-512.

Teno, Joan M and others. "Role of Written Advance Directives in Decision Making. Insights from Qualitative and Quantitative Data." *Journal of General Internal Medicine* 13, no. 7 (1998): 439-446.

Teno, Joan and others. "Advance Directives for Seriously Ill Hospitalized Patients: Effectiveness with the Patient Self-determination Act and the SUPPORT Inter- vention. SUPPORT Investigators. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment." *Journal of the American Geriatrics Society* 45, no. 4 (1997): 500–507.

Teres, Daniel. "Trends from the United States with end of life decisions in the intensive care unit." *Intensive Care Medicine* 19, no. 6 (1993): 316-322.

Thom David H, and Babatunde Campbell. "Patient-physician trust: an exploratory study." *The Journal of Family Practice* 44, no. 2 (1997): 169-176.

Thom David H, and others. "Physician trust in the patient: development and validation of a new measure." *Annals of Family Medicine* 9, no. 2 (2011): 148-54.

Thomas Carl and others. "Place of death: preferences among cancer patients and their carers." *Social Science & Medicine* 58, no. 12 (2004): 2431–2444.

Thomas, Carol. "Companions through cancer: The care given by informal carers in cancer contexts." *Social Science and Medicine* 54, no. 4 (2002): 529–544.

Thomaska, David C. "Proposing a new agenda: bioethics and international human rights." *Cambridge Quarterly of Healthcare Ethics : CQ : the International Journal of Healthcare Ethics Committees* 10, no. 3 (2001): 299-310.

Tibaldi Giuseppe and others. "From treatment adherence to advanced shared decision making: new professional strategies and attitudes in mental health care." *Current Clinical Pharmacology* 6, no. 2 (2011): 91-99.

Toro, L. Blanco and others. "Perfil del cuidador principal del enfermo en situación terminal y análisis del riesgo de desarrollar duelo patológico." *Medicina Paliativa* 14, no. 3 (2007): 1-5.

Tsevat, Joel and others. "Health values of hospitalized patients 80 years or older. HELP Investigators. Hospitalized Elderly Longitudinal Project." *Journal of the American Medical Association* 279, no. 5 (1998): 371-375.

V

Van Delden, Johannes J. and others. "Do-not-resuscitate decisions in six European countries." *Critical Care Medicine* 34, no. 6 (2006): 1686-1690.

Van der Burg, Wibren. "Law and Bioethics." In *A companion to Bioethics,* edited by Kuhse Helga and Peter Singer. Oxford: Blackwell, 1998.

Venkatasalu, Munikumar R. and others. "Understanding the meaning of end-of-life discussions and related decisions among older South Asians living in East London: a qualitative inquiry." *British Medical Journal Supportive & Palliative Care* 1, no. 1 (2011): 79–80.

Vezzoni, Cristiano. *The legal status and social practice of treatment directives in the Netherlands*, Groningen: RUG (Rijksuniversiteit Groningen), 2005.

Vimercati, Benedetta. "Amministratore di sostegno e consenso informato: scelte di politica legislative e case law a raffronto (parte I)." *Rivista Italiana di Medicina Legale e del Diritto in Campo Sanitario* 33, no.1 (2011): 129-173.

Vrakking, Astrid and others. "Comment on "Attitudes of European physicians, nurses, patients, and families regarding end-of-life decisions: the Ethicatt study" by Sprung et al." *Intensive Care Medicine* 33, no. 4 (2007): 747.

W

Walter, Jennifer K. and Lainie F. Ross. "Relational Autonomy: Moving Beyond the Limits of Isolated Individualism" *PEDIATRICS* 133, no. 1 (2014): S16-23.

Wiesemann, Claudia and Alfred Simon. *Patientenautonomie: Theoretische Grundlagen - Praktische Anwendungen.* Münster: Mentis-Verlag, 2013.

Wiesing, Urban and others. "A new law on advance directives in Germany." *Journal of Medical Ethics* 36, no. 12 (2010): 779–783.

Wiesing, Urban and others. "A new law on advance directives in Germany." *Journal of Medical Ethics* 36, no. 12 (2010): 779–783.

Wilson, Fiona and others. "Autonomy and choice in palliative care: time for a new model?" Journal of Advanced Nursing 70, no. 5 (2014): 1020-1029.

Whiting, Raymond A. "A natural Right to die." *Omega (Westport)* 32, no. 1 (1995-1996): 11-26. Witting, Marsha N. and others. "Stability of preferences for end-of-life treatment after 3 years of follow-up: the Johns Hopkins Precursors Study." *Schistosomiasis* 168, no. 19 (2008): 2125-2130.

Witting, Marsha N. and others. "Stability of preferences for end-of-life treatment after 3 years of follow-up: the Johns Hopkins Precursors Study." *Schistosomiasis* 168, no. 19 (2008): 2125-2130.

Wolf, Susan M. and others. "Sources of concern about the Patient Self-Determination Act." *New England Journal of Medicine* 325, no. 23 (1991): 1666–1671.

World Health Organisation. "European health report 2012 charting the way to well-being." http://www.euro.who.int/__data/assets/pdf_file/0004/197113/EHR2012-Eng.pdf

Worth, Allison and others. "Vulnerability and access to care for S. Asian Sikh and Muslim patients with life limiting illness in Scotland: a prospective longitudinal qualitative study." *BMJ : British medical journal / British Medical Association* 338, no. 3 (2009): b183.

Woods Simon. *Death's Dominion: Ethics at the End of Life.* Maidenhead: Open University Press, 2007.

Z

Zelderloo, Luk. "Autonomy, belonging and interdependency." *International Journal of Integrated Care* 9 (Suppl) (2009): e79.

Zerwekh, Joyce V. *Nursing Care at the End of Life Palliative Care for Patients and Families.* Philadelphia: F. A. Davis Company, 2005.

Zullo, Silvia. "Interruzione delle cure e morte cerebrale. Profili bioetici e filosofici." In *Bioetica e Biodiritto Problemi, casi e materiali*, edited by Carla Faralli, 122 - 131. Torino: Giappicchelli Editore, 2010.

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Veshi, Denard and Gerald Neitzke. "Advance Directives in some Western European Countries: a Legal and Ethical Comparison between Spain, France, England and Germany." (2015) *European Journal of Health Law* 22, no.4 (2015): 321-345.

Veshi, Denard and Gerald Neitzke. "Living wills in Italy: ethical and comparative law approaches." *European Journal of Health Law* 22, no. 1 (2015): 38-60.

Veshi, Denard. "Withdrawing Treatment from Incompetent Patients in Italy: The Case of Eluana Englaro." *Asian Bioethics Review* 6, no. 4 (2014): 402-408. (Commentary).

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Annex*

Italian Bill 2350 ***Norms in Matter of Therapeutic Alliance, Informed Consent and Advance Treatment Directives*** as approved by the Chamber of Deputies on 12 July 2011.

Article 1 (Protection of life and health)

1. The present law, by taking into consideration the principles established in articles 2 [protection of inviolable rights], 3 [principle of equality], 13 [protection of personal freedom], and 32 [protection of the right to health] of the [Italian] Constitution:

a) recognizes and protects human life as an inviolable and unavailable right, guaranteed also in the terminal phase of life and in cases when the person is no longer competent, until death is verified according to the law;

b) recognizes and protects the dignity of every person as a priority over society's interest and over technological and scientific applications;

c) prohibits under articles 575 [homicide], 579 [homicide by request of the victim] and 580 [aiding or incitement suicide] of the [Italian] Penal Code every form of euthanasia, assistance or aid to suicide, considering medical activity

* This is a translation into English of the Italian Bill 2350 done by the author.

and assistance to patients exclusively aims to protect life and health as well as to relieve suffering;

d) compels doctors to inform patients on the most appropriate medical treatments, except for cases established in article 2, section 4, and on the prohibition on every form of euthanasia, recognizing as a priority the therapeutic alliance between the physician and the patient, which becomes particularly significant at the end of life;

e) recognizes that no medical treatment can be performed without informed consent as established in article 2, by considering that health must be protected as a fundamental individual right and as a collective interest, and nobody can be obliged to [receive] a specific medical treatment, except under a provision of the law and with the limits imposed by the respect for the human person;

f) guarantees that in cases of patients at the end of life or in a condition of imminent death, the physician must abstain from extraordinary treatments which are disproportional compared to the patient's clinical conditions or to the objectives of cure.

2. The present law guarantees, within the framework of those interventions already established by the current legislation, social and economic policies aiming to take care of patient, in particular of people who are incompetent, be they Italian citizens, foreigners or stateless persons, and of their families.

3. Patients mentioned in letter f) of section 1 have the right to be assisted through appropriate therapy against pain in accordance with palliative care protocols, established in the current legislation.

Article 2 (Informed consent)

1. Except for the cases established by law, every medical treatment is performed after explicit and present informed consent given freely and consciously by the patient.

2. The expression of informed consent is preceded by correct information provided in a compressible manner by the physician in charge of the patient regarding the diagnosis, prognosis, scope and nature of the proposed medical treatment, foreseeable benefits and risks, possible side effects, as well as possible alternatives and the consequences of refusal of treatment.

3. The therapeutic alliance built within the physician-patient relationship according to section 2 can be expressed, if the physician considers it necessary or if the patient requests it, in a document on informed consent, signed by the patient and the physician. This document is included in the medical record upon request of the doctor or of the patient.

4. The patient retains the right to refuse in whole or in part the information he or she is entitled to receive. The refusal can occur at any moment and must be expressed in a document signed by the interested person and becomes an integral part of the medical record.

5. Informed consent to medical treatment shall always be revocable, also partially. Such a revocation shall be noted in the medical record.

6. In the case of an interdicted person, informed consent is given by the legal tutor who signs the document. In the case of an inability or an emancipated minor, informed consent is jointly given by the interested person and the curator. In case of a nomination of a support guardian where the decree of nomination establishes the assistance or the representation in situations of health care, informed consent is also given by the support guardian or only by the support guardian. The decision of these subjects also includes the provisions of article 3 and it is taken with the sole aim of protecting the health and life of the inability.

7. Informed consent to medical treatment of minors is given or refused by those who exercise parental authority or the guardianship after carefully listening to the wishes and requests of the minor. The decision of these subjects is taken with the sole aim of protecting the life and the psycho-physical health of the minor.

8. For all the interdicted or inability the health-care personnel is obliged to, in absence of a declaration of advance treatment directives, operate by always considering the sole aim of protecting the life and health of the patient.

9. Informed consent to medical treatment is not required where in the case of an emergency there is a acute risk to the patient's life.

Article 3 (Contents and limits of the advance treatment directive)

1. In an advance treatment directive the declarant, who is competent and has received complete medical and clinical information with regards to a possible future permanent loss of competency, expresses orientations and useful information for the physician relating to therapeutic treatments in conformity with the provisions of the present law.

2. The advance treatment directive can contain an explicit renunciation of any or of some specific forms of therapeutic treatments as such of disproportionate character or experimental nature.

3. The advance treatment directive cannot contain instructions corresponding to the crimes proscribed by articles 575, 579, and 580 of the [Italian] Penal Code.

4. Also in respect of the United Nations Convention on the Rights of Persons with Disabilities, signed in New York on 13 December 2006, alimentation and hydration, in the various forms that science and technology may provide to the patient, must be maintained until the end of life, except in cases where they are no longer efficacious in providing the patient during the terminal phase with the nutritional factors necessary for the essential physiological functions of the body. They shall not be the object of an advance treatment directive.

5. The advance treatment directive is executive when the person is in a state of permanent incapacity to understand the information regarding medical treatments and their consequences due to an assessed absence of integrative cortical-subcortical brain activity and, therefore, [the patient] cannot make

decisions about him or herself. Such an assessment is certified by a collegial medical team composed, without additional or new costs for the public finances, of an anesthesiologist-intensive care doctor, a neurologist, the physician in charge and a specialist of the disease affecting the patient. These physicians, except the physician in charge, are appointed by the directive board of the medical facility where the patient is hospitalized or, in case of necessity, by the relevant local health authority.

Article 4 (Form and duration of the declaration of advance treatment directives)

1. Advance treatment directives do not have legally-binding force, [they] are redacted in written form, dated and signature by the adult interested party, who is competent and has received complete medical and clinical information, and [they] are collected exclusively by the general practitioner who also signs them.

2. Advance treatment directives shall be made in full freedom and consciousness, as well as signed with an autograph signature. Eventual declarations of intents or orientations expressed by the interested party in ways different from the forms and modalities established by the present law have no value and cannot be used to reconstruct the patient's will.

3. Unless the interested party has become incapable, the advance treatment directive is valid for five years, starting from the date of the drafting of the act according to section 1, after which it loses any efficacy. The advance treatment directive can be renewed several times, in the same form and modalities as established in sections 1 and 2.

4. The advance treatment directive can be revoked or modified at any time by the interested person. The revocation, even partially, of the advance treatment directive must be signed by the interested person.

5. The advance treatment directive must be included in the medical record from the moment it assumes importance from a clinical point of view.

6. In the case of an emergency or when the patient is in an immediately life-threatening condition, the advance treatment directive does not apply.

Article 5 (Assistance to patients in a vegetative state)

1. In order to guarantee and assure equitable access to assistance and quality of care, the assistance to patients in a vegetative state represents an essential level of assistance according to the modalities established in the [Italian] Decree of the President of Ministers of 29 November 2001, published in the ordinary supplement of the [Italian] Official Gazette no. 33 of 8 February 2002. Healthcare assistance to patients in a vegetative state or affected by other neurological conditions is provided through hospitals or residential and home care services according to the modalities provided in the mentioned Decree of the President of Ministers and the agreement between the [Italian] Ministry of Health, the Regions and the Autonomous Provinces of Trento and Bolzano on the Guidelines for assistance to patients in a vegetative state and minimally conscious states, approved by the Unified Conference established on article 8 of the [Italian] Legislative Decree no. 281 of 28 August 1997 and following amendments, during the meeting of 5 May 2011. Home care is, generally, provided by the local health authority with territorial jurisdiction over the place where the patient in a vegetative state is.

Article 6 (Surrogate)

1. In the advance treatment directive the declarant can appoint a competent adult as surrogate who accepts the appointment by signing the declaration.

2. The declarant who has appointed a surrogate can substitute him or her according to the same modalities followed for his or her appointment at any time without any obligation to give reasons for such a decision.

3. The surrogate, if nominated, is the only person who is legally authorized to interact with the physician and is assumed to act exclusively in the best interest of the patient, acting always and solely in accordance with the wishes

legitimately expressed by the patient in his or her advance treatment directive.

4. The surrogate is entitled to ask for and to receive from the physician any information on the state of health of the declarant.

5. The surrogate, if nominated, undertakes to monitor that the best available palliative treatments are administered to the patient, avoiding the creation of situations of therapeutic futility or therapeutic abandonment.

6. The surrogate, if nominated, undertakes to verify carefully that no situation amounting to the crimes established by articles 575, 579, and 580 of the [Italian] Penal Code affects the patient.

7. The surrogate can renounce the appointment in writing, communicating it to the declarant or, if the person is incompetent, to the physician in charge of the therapeutic treatment.

8. In case no surrogate has been appointed, the tasks provided in sections 3, 4, 5 and 6 of this article are undertaken by the patient's relatives as indicated by Book II, title II, headings I and II of the [Italian] Civil Code.

Article 7 (The role of the physician)

1. The orientations expressed by the person in his or her advance treatment directive are taken into consideration by the physician in charge who, after listening to the surrogate, annotates in the medical record the reasons why he or she does or does not follow them.

2. In case the physician in charge decides not to follow the orientations expressed by the patient in the advance treatment directive, [he or she] must consult the surrogate or the patient's relatives, as indicated by Book II, title II, headings I and II of the [Italian] Civil Code, express in detail what motivated his or her decision and sign the medical record or in a separate document, which is annexed to the advance treatment directive.

3. The doctor cannot take into consideration directions that are meant to cause the death of the patient or are in conflict with the law or medical deontology. The orientations are evaluated by the physician, [after] listening to the surrogate, according to science and conscience, in application of the principle of the inviolability of human life and the protection of health and life, according to the principles of precaution, proportionality and prudence.

Article 8 (Final provisions)

1. A Registry of advance treatment directives is established within a single national information archive. The holder entitled to the processing of data inserted in this archive is the [Italian] Ministry of Health.

2. By regulation to be adopted according to article 17, section 3, of [Italian] Law No. 400 of 23 August 1988, within one hundred twenty days from the date of entry into force of the present law, the [Italian] Ministry of Health, [after] listening to the Guarantor for the protection of personal data, shall provide the technical rules and the modalities of access, conservation and consultation of the Registry established in section 1. The decree also establishes the terms and forms according to which citizens can write an advance treatment directive at the general practitioner's office and register it [the directive] at the local health authority, the modalities of conservation of advance treatment directives at the local health authority and the modalities for the telematic transmission to the Registry mentioned in section 1. Every information concerning the possibility to make an advance treatment directive are also made available on the website of the [Italian] Minister of Health.