

Medical treatment and expression of the consent of the elderly not able to consent: a comparative analysis of the case law in the countries of the Council of Europe.

By Elena Falletti, Carlo Cattaneo – LIUC University, Italy

The European Convention on Human Rights and Biomedicine, signed in 1997 in Oviedo, promoted by the Council of Europe and ratified by 29 of its Member Countries, is a relevant legal instrument to discipline medical treatments, specifically the giving of a free and informed consent to medical treatments. Article 6.3 establishes the protection of persons not able to consent. In this case “ *a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law*”. Elderly people suffering from irreversible, debilitating and degenerative diseases, such as senile dementia, depression, cancer, Alzheimer's or Parkinson's diseases, which can cause loss of lucidity, are involved in this kind of regulation. These elderly patients should be subjected to chronic therapies. In this perspective the protection of their true and informed consent becomes a main issue and it should be protected relating the protection of their dignity, through the fair access to welfare provisions, the access to justice and the prevention of abuse and violence, specially when forced in therapies or medical treatments.

The aim of this paper is to investigate the regulation and the case law related to the application of article 6.3 in the Member States who ratified the Convention on Human Rights and Biomedicine.

Key Words: Informed consent, Medical therapies, Chronic Illness, Protection of dignity, Mental disability

1. Introduction.

In recent years, the prolongation of human life has caused the growing percentage of elderly people worldwide and ethical, and consequently legal issues concerning care for older people are set to become more predominant. According to data analyzed in 2011, over the past two decades, the share of the population aged over 65 years in the EU-27 population increased by 4.4 percentage points¹ from 13.9% in 1991 to 17.5% in 2011. Population aging, healthcare, and working condition improvements are strictly connected. However, during the mature stage of their existence, many

¹ Eurostat, European Commission, (June, 14th 2014), Population structure and ageing, http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Population_structure_and_ageing

elderly people could suffer from incurable diseases such as diabetes, senile dementia, Parkinson's or Alzheimer's syndromes, and other chronic maladies. Recently, the relationship between doctors and their patients has been under focus, especially for the increasing relevancy of joint decision-making by doctor and patient, rather than physician solo decision-making, and in cases of conflict recognizing the patient's dominion over his or her own body².

In common law legal culture, the concept of self-determination is deeply rooted³, for instance Justice Cardozo exposed the concept of self-determination in "Schloendorff v. New York Hospital"⁴ by affirming that "every human being of adult years and sound mind has a right to determine what shall be done to his body." In continental Europe, medical paternalism has experienced more conceptual resistance, because the doctor was the only one able for competence and authority to decide concerning the patient's therapies, whose only goal was his or her recovery⁵. One of the most important legal instruments used to introduce the concept of informed consent in European legal systems is the European Convention on Human Rights and Biomedicine⁶. This Convention, promoted by the Council of Europe and ratified by 26 of its 47 Member States⁷, constitutes the first and at the moment only attempt to establish a binding European legal instrument that covers the core areas of medicine and scientific research, establishing a "minimum standard level" of human rights protection in biomedical treatments in Europe.⁸ It has been drawn on some articles of the European Convention on Human Rights and Fundamental Freedoms, especially those related to "rights to life, to physical integrity and to privacy, the prohibition of inhuman or degrading treatment and of any form of discrimination"⁹, and on the case law produced on it by the European Court of Human Rights. Its principal aim is to improve in protection of individual dignity and self-determination, in fact it ensures that in any case the individual interest prevails against scientific or social interests. Its main issues are related to informed consent, access to medical data, predictive genetic tests, intervention on human genome, medical research on persons, human organs and human tissues.

² Susan M. Wolf, Doctor and Patient: An Unfinished Revolution, (June 14th 2014) 2006, <http://ssrn.com/abstract=1729392>.

³ Natanson v. Kline, 350 P.2d 1093, 1104 (Kan. 1960); Cruzan v. Missouri Dep't of Health, 497 U.S. 261, 288 (1990)
⁴ 211 N.Y. 125 (1914).

⁵ VINCENZO M. PALMIERI, *MEDICINA FORENSE*, I, 1964, 67; Stefano Rossi, *Consenso informato* in DIGESTO DELLE DISCIPLINE PRIVATISTICHE, SEZIONE CIVILE, AGGIORNAMENTO VII, 183 (Rodolfo Sacco, ed., 2012).

⁶ 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, Oviedo, 4.IV.1997, <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>.

⁷ See supra paragraph 5.

⁸ Siegmund Simonsen, *European Integration – A Case Example from Biomedical Research Law*, in NORDIC HEALTH LAW IN A EUROPEAN CONTEXT: WELFARE STATE PERSPECTIVES ON PATIENT'S RIGHTS AND BIOMEDICINE, 262 (Elizabeth Rynninf & Mette Hartlev eds., 2011).

⁹ Roberto Andorno, *The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law*, JIBL (Journal of international biotechnology law), 2005, 133.

The aim of this paper is to verify the application of Article 6.3 of the Convention on Biomedicine and Human Rights to elderly people affected by chronic diseases and unable to decide for themselves. Firstly, the paper will present the main disposition of the Convention related to the care of the patient and secondly, it will verify the case law of the European countries that ratified the Convention, if it exists.

2. Medical treatments, right to be informed and protection of human dignity

Both medical treatments and the expression of the ability of elderly people to express their consent are issues arising in two areas¹⁰: on the one hand the sphere of human rights, in that those rights safeguard the dignity of the human being, and the more specific area of bioethics in situations of high vulnerability; and on the other hand, the balance between the protection of the elderly people's dignity and the scientific and medical progress¹¹. In this sense, the purpose of Article 1 of the Convention on Human Rights and Biomedicine is to “protect the dignity and identity of all human beings and guarantee everyone respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine”.

According to Article No. 2 of the Convention

“[Primacy of the human being.] The interests and welfare of the human being shall prevail over the sole interest of society or science”.

This principle is very general and its purpose is to avoid any kind of exploitation of the patient, especially in the interest of third parties such as family or caregivers and public health policies related to management of the economic resources for balancing accounts¹², considering “the demographic weight” of extreme old age and disabled people in economic terms¹³. In such cases, the main focus is taking care and respecting dignity of vulnerable patients¹⁴. It could be possible that the end of life decision-making is involved, since in many situations the refuse of medical treatment could cause the death of the patient. In these cases, the above mentioned principle imposes that the patient must be at the centre of the health provision and his or her wishes, when

¹⁰ Isabelle Erny, What is at Stake in the Symposium in Relation to the Principles of the Convention on Human Rights and Biomedicine, *Symposium on decision making process regarding medical treatment in end of life situations, 30 November – 1 December 2010, Palais de l'Europe, Strasbourg, France*, (June 14th, 2014) http://www.coe.int/t/dg3/healthbioethic/Activities/09_End%20of%20Life/default_en.asp, 17.

¹¹ Isabelle Erny, *supra*, n. 10.

¹² COMITATO NAZIONALE DI BIOETICA, LE CONDIZIONI DI VITA DELLA DONNA NELLA TERZA E QUARTA ETÀ: ASPETTI BIOETICI NELLA ASSISTENZA SOCIO SANITARIA, 20 (2010).

¹³ Isabelle Erny, *supra*, n. 10.

¹⁴ Chris Gastmans, *Dignity-enhancing nursing care: a foundational ethical framework*, Nurs Ethics, 2013 Mar;20(2):142-9.

expressed, must take precedent¹⁵, even if the patient refuses saving-life treatments. According to the principle of self-determination, the patient has the right to participate in decision-making in his or her own interest¹⁶.

If the patient is no longer able to take part in the decision-making process, his or her wishes, such as the advanced instructions or information provided by his or her legal representative, and relatives, must be arranged for his or her protection¹⁷. If the person's wishes cannot be determined, the pursuing of the patient's best interest

“implies that the decision take account of his/her well-being and quality of life [...] which may take precedent over treatment which has become futile or disproportionate”¹⁸

In any case, the terminally ill patient should not to be abandoned: he or she must have access to the most appropriate care for such kind of condition, accessing pain treatment, necessary nursing care and palliative care.

When the patient is particularly vulnerable, his or her the right to privacy is a very important issue because his or her sphere of intimate and private life can be restricted from the moment of his or her hospitalisation or the intervention of health professionals. In this perspective, the respect of the patient's self-determination should be realized through keeping the patient informed according to his or her degree of comprehension and listening capacity, in consequence of his or her condition¹⁹. However, this kind of information must be adapted to the specific patient's case, ascertaining what he or she “wishes to hear or is able to hear without being made even more fragile”²⁰. In this case, the Explanatory Report to the Convention explains that the medical information has to be accurate and complete, but limited to the elements effectively comprehensible to the patient, according to his or her cultural and psychological conditions. Therefore reporting of data such as percentages of mortality, failures and other data related to scientific aspects of the treatment should be avoided²¹.

¹⁵ Isabelle Erny, *supra*, n. 10.

¹⁶ RONALD B. DWORKIN, *LIMITS: THE ROLE OF THE LAW IN BIOETHICAL DECISION MAKING*, (1996), 117; Massimo Franzoni, *Dal consenso all'esercizio dell'attività medica all'autodeterminazione del paziente*, *Resp. civ.*, 2012, 2; Alessandra Pioggia, *Consenso informato e rifiuto di cure: dal riconoscimento alla soddisfazione del diritto*, *Giornale Dir. Amm.*, 2009, 3, 267.

¹⁷ Cass. (It.), 16.10.2007, n. 21748; Isabelle. Erny, *supra*, n. 10.

¹⁸ Isabelle Erny, *supra*, n. 10.

¹⁹ Mariassunta Piccinni, *Autodeterminazione e consenso nell'incapacità e capacità non completa. 3.2 Relazione terapeutica e consenso dell'adulto "incapace" dalla sostituzione al sostegno*, in *I DIRITTI IN MEDICINA*, 390 (Leonardo Lenti & Paolo Zatti, eds. 2011).

²⁰ Isabelle Erny, *supra*, n. 10.

²¹ ILYA R. PAVONE, *LA CONVENZIONE EUROPEA SULLA BIOMEDICINA*, 51 (2009); 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, Apr. 2, 1997, Explanatory Report, (June 14, 2014) <http://conventions.coe.int/Treaty/EN/Reports/Html/164.htm>.

3. The problem of consensus to medical treatment of elderly, competent or incompetent, patients

Article 6.3 of the Convention on Human Rights and Biomedicine states that in the care of

“a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take in part (...) the authorization procedure”.

So, when an adult individual no longer has the capacity to give consent because of a mental disability, a shock or a disease, medical treatment may be carried out according to the authorisation of his or her representative, if appointed or informally involved²², or an authority provided by law²³. However, the person affected by the incapacity shall as far as possible be involved in the medical decision-making, respecting his or her best interest²⁴. In fact, the consent on behalf of another individual is often a source of problems, especially in case of the decision to limit or discontinue medical treatment of an unconscious or chronically or terminally ill patient²⁵. However, medical professionals have to make responsible efforts to ensure that

“as far as possible, patients and participants have a sufficiently full and realistic understanding of proposed interventions and that they are making choices free from external pressures, even where these pressures are well-meaning²⁶”

According to the Explanatory Report of the Convention, physicians are not always bound to respect the opinion of the incapable or incompetent person's legal representative, because they have to operate following “the best interest of the person”, even if this means to act in a different way²⁷. Nevertheless, according to some scholars, a judicial intervention does not seem to be the best solution for incompetent or incapable persons. Indeed, a doctor should know his or her patient and his or her personal and therapeutic experiences with all related clinical and psychological problems, so, he or she has better elements to decide on the specific case than to a third party, such as a judge,

²² Sjef Gevers & Joseph Dute & Herman Nys, *Surrogate Decision-making for Incompetent Elderly Patients: The Role of Informal Representatives*, Eur J Health Law. Mar;19(1):61-68 (2012).

²³ Isabelle Erny, supra, n. 10.

²⁴ Ilya R. Pavone, supra n. 21.

²⁵ Isabelle Erny, supra, n. 10.

²⁶ NUFFIELD COUNCIL ON BIOETHICS, *NOVEL NEUROTECHNOLOGIES: INTERVENING IN THE BRAIN*, 93-94, (2013).

²⁷ Ilya R. Pavone, supra, n. 21.

who knows only some elements of the specific case²⁸. In this sense, some scholars have serious doubts about the the opportunity of judicial intervention in such a sensitive area, highlighting the risk of legalization of medical decisions²⁹.

However, on the one hand there is the physician's ability/material capacity to cure, and on the other hand there is his or her power to cure. In the absence of the patient's consent, even if actually he or she possesses the professional competence to properly enforce the therapy, the physician does not have the full power to cure. These two operational levels should be separate. The first one is related to the technical and professional feasibility to provide care based on the best science and experience available; while the second one is related to the authority required in order to legitimize the concrete application of the available medical treatments. Only the patient could attribute this authority to the doctor through his or her manifestation of informed consent, and this same authority ceases in the moment in which the patient refuses or withdraws such consent³⁰.

4. **Situations in which elderly patients could be involved under the case law of the European Court of Human Rights.**

According to the recent case law of the ECtHR, it is possible to argue that the provisions of the European Convention of Human Rights and Fundamental Freedoms (ECHR) constitute a kind of European common law in the field of fundamental rights.³¹ Despite the presence of the margin of appreciation, state parties to the Convention could not escape the implementation of this "lowest common denominator".³² For the purpose of this research it is useful to check how the principles are developed in the situations in which an elderly patient, whether or not capable of consent, may be involved in the decision on medical treatment, can be distinguished in³³:

- **refusal of hospitalization.** Elderly patients may refuse to be checked into a hospital or a nursing facility, because they prefer to stay at their home according to their habits. Nevertheless, according to the perspective of third parties, such as their family or their doctors, could be different and this refusal could be seen as a loss of chance since not all therapies

²⁸ Ilya R. Pavone, *supra*, n. 21.

²⁹ Jan K. M. Gevers, *The European Court of Human Rights and the Incompetent Patient*, in *Eur J Health Law*, 225-229 (2004).

³⁰ COMITATO NAZIONALE DI BIOETICA, RIFIUTO E RINUNCIA CONSAPEVOLE AL TRATTAMENTO SANITARIO NELLA RELAZIONE PAZIENTE-MEDICO, 7 (2008).

³¹ Marta Cartabia, *Fundamental Rights and the Relationship among the Court of Justice, the National Supreme Courts and the Strasbourg Court*, in 50TH ANNIVERSARY OF THE JUDGMENT VAN GENT EN LOOS, 1963-2013, (Antonio Tizzano, Juliane Kokott, Sacha Prechal eds), 159 (2013).

³² Catherine Botoko-Clayesen, *Engagements Universels et Identité Européenne des Droits de l'Homme*, *Revue trimestrielle des droits de l'homme*, 947 (2001).

³³ COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE POUR LES SCIENCES DE LA VIE ET DE LA SANTÉ, AVIS N° 87, REFUS DE TRAITEMENT ET AUTONOMIE DE LA PERSONNE (14 June 2014) <http://www.ccne-ethique.fr/sites/default/files/publications/avis087.pdf>, 10-12 (2005).

could be given at home. The European Court of Human Rights stated that the forced hospitalization of an elderly woman suffering mental health problems infringes Article 5 of European Convention of Human Rights, protecting the right to liberty and security³⁴.

- **Refusal to receive a drug or a medical treatment.** Self-determination about health condition is one of the most controversial issues in the public bioethical debate. In the specific case the self-determination of older people³⁵, the issues of capacity of the patient, the quality of life and life expectancy strongly enter into the debate. In front of the European Court of Human Rights, the German Government, in the case Koch v. Germany³⁶ has argued that «granting unrestricted access to a fatal drug could create an appearance of normality, which could lead to a sense of pressure on the part of the elderly and the seriously ill “not to become a burden”³⁷.» To this risk the European Court of Human Rights argued “that the domestic courts’ refusal to examine the merits of the applicant’s motion violated the applicant’s right to respect for his private life under Article 8 of the Convention”³⁸.
- **Refusal of force-feeding (i.e. introduction of the PEG tube).** In cases of malnutrition consequent from chronic diseases, such as anorexia³⁹, or permanent vegetative state⁴⁰, according to some court decisions the protection of the best interest of the patient prevail over his or her willingness to refuse the PEG tube, on the ground that the relevant factors are “almost exactly” in equilibrium and the judge declared that he would carefully balance tips in the direction of life-preserving treatment, because of the patient lacked capacity to make

³⁴ Zagidulina v. Russia, Eur. Ct. H. R. 2 May 2013, App. No. 11737/06. In this case, the patient was born in 1935 and lives in Moscow. Since 1987 she has been registered as an outpatient of Psychiatric Hospital No. 5 in Moscow. Prior to the events in question, she had never been hospitalised in a psychiatric facility. The European Court of Human Rights stated that: “(I)n the light of the vulnerability of individuals suffering from mental disorders and the need to adduce very weighty reasons to justify any restriction of their rights, the proceedings leading to the involuntary placement of an individual to a psychiatric facility must necessarily provide clearly effective guarantees against arbitrariness. This position is supported by the fact that hospitalisation in a specialised medical institution frequently results in an interference with an individual’s private life and physical integrity through medical interventions against the individual’s will”.

³⁵ In Re C (Adult: Refusal of Treatment) [1994] 1 WLR 290; NHS Trust v K & Ors [2012] EWHC 2922 (COP) (15 October 2012); Heart of England NHS Foundation Trust v JB [2014] EWHC 342 (COP) (17 February 2014).

³⁶ The applicant's wife suffered from a chronic and fatal disease (sensorimotor quadriplegia). She would to commit suicide, but the national authorities, even the Bundesverfassungsgericht, (Case No. 1 BvR 1832/07) the Federal Constitutional Tribunal, ruled that her case was inadmissible. The couple went in Switzerland, where the law allows assisted suicide. After his wife's death, the applicant continued the legal proceeding, but for the second time, the German courts stated that he did not “herited” any rights enjoyed by his former wife. However, the European Court of Human Rights disagreed because he was married to his wife for 25 years and, he was immediately involved in the realisation of her wife's wishes to access to lethal drugs. According Article 8 of the European Convention on Human Rights, the defendant State, Germany, failed to guarantee to the applicant's case to be heard on the merit. J. Dute, ECHR 2013/1 Case of Koch v. Germany, 19 July 2012, no. 497/09 (Former Fifth Section), Eur J Health Law. 2013 Mar;20(1):79-82.

³⁷ Koch v. Germany, Eur. Ct. H. R. 19 July 2012, App. No. 497/09.

³⁸ Koch v. Germany, Eur. Ct. H. R. 19 July 2012, App. No. 497/09.

³⁹ Re E (Medical treatment: Anorexia) (Rev 1) [2012] EWHC 1639 (COP) (15 June 2012).

⁴⁰ W v M & Ors [2011] EWHC 2443 (Fam) (28 September 2011)

decision about life-sustaining treatment. Then, “*it is lawful and in her best interests for her to be fed, forcibly if necessary. I find that the resulting interference with E's rights under Articles 8 and 3 is proportionate and necessary in order to protect her right to life under Article 2*”⁴¹.

- **Refusal of tracheostomy (i. e. creation of a surgical airway in the cervical trachea and placing a cannula externally into it).** A large number of patients with chronic obstructive pulmonary diseases need tracheostomy, at some point in the course of their disease, to improve their chances of ventilation. However, these patients with a chronic disease could be worse and often they do not support the idea of a tracheostomy that could limit their personal relationships by the change or loss of voice⁴². The lawfulness of refusal of life-saving treatment, as tracheostomy is, is widely debated in Europe. Scholars observe that there are three main approaches to the valuation of human life: vitalism⁴³, quality of life⁴⁴ and the inviolability of life⁴⁵. Case law in this matter is very divergent. The European Court of Human Rights, in the well-known *Pretty* case, stated that Article 2 ECHR protects human life, cannot “without a distortion of language, be interpreted as conferring the diametrically opposite right, namely [the] right to die; nor can it create a right to self-determination in the sense of conferring on an individual the entitlement to choose death rather than life”⁴⁶. National courts said that such decision is related to the fundamental rights to self-determination⁴⁷ and privacy protection⁴⁸.
- **Refusal of the introduction of the cannula.** It is a tube for insertion into the body to draw off fluid for rehydrating the patient or to introduce medication. This issue is strictly connected to self-determination of the patient from his or her therapies, but objectives treatment must always be weighed in order to evaluate how the person perceives this therapeutic modality.
- **refusal of transfusion.** This issue is specific to religious beliefs of Jehovah's Witnesses, when refusal of a blood transfusion might have fatal consequences. This represents a complex issue involving different elements. On the one hand there are elements related to

⁴¹ Re E (Medical treatment: Anorexia) (Rev 1) [2012] EWHC 1639 (COP) (15 June 2012).

⁴² COMITÉ CONSULTATIF NATIONAL D'ETHIQUE POUR LES SCIENCES DE LA VIE ET DE LA SANTÉ, AVIS N° 87.

⁴³ According to it, “the human life is the supreme good and one should do ever everything to preserve it”. JOHN KEOWN, *THE LAW AND ETHICS OF MEDICINE. ESSAYS ON THE INVIOABILITY OF HUMAN LIFE*, 4 (2012).

⁴⁴ “This valuation of human life grounds the principle that, because certain lives are not worth living it, it is right intentionally to terminate them, whether by act or omission”, JOHN. KEOWN, *supra*, n. 43, 5.

⁴⁵ “Human is a basic, intrinsic good. All human beings possess, in virtue of their common humanity, an inherent, inalienable, and ineliminable dignity”, JOHN. KEOWN, *supra*, n. 43, 5.

⁴⁶ *Pretty v. United Kingdom*, Eur. Ct. H. R., 29 April 2002, App. No. 2346/02.

⁴⁷ Tribunale di Modena, (It.), 13 May 2008.

⁴⁸ *Purdy, R (on the application of) v Director of Public Prosecutions* [2009] UKHL 45 (30 July 2009).

the concrete effects religious beliefs have on the believer's life and body. While, on the other hand there is the risk that the will of the believer, competent or incompetent, can be influenced by the pressures of the religious community to which he or she belongs. Both international⁴⁹ and national⁵⁰ courts decided on such kind of cases. The prevailing orientation states that the will and the choices of the patient belonging to the community of Jehovah's Witnesses must be free from influences in his or her self-determination.

5. Ratification of the Convention on Human Rights and Biomedicine in the Member States of the Council of Europe

The Convention was signed in Oviedo on 4 April 1997, the condition for its entry into force was its ratification by four member states. It was reached on 1 December 1999. As of today, only 29 of the 47 Member States have fully ratified it. They are Albania, Bosnia and Herzegovina, Georgia, Iceland, Moldova, Montenegro, Norway, San Marino, Serbia, Switzerland, The Former Yugoslav Republic of Macedonia, Turkey, while among the Member States of both Council of Europe and European Union⁵¹ they are: Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Latvia, Lithuania, Portugal, Romania, Slovakia, Slovenia, Spain. It was only signed but not yet ratified by Italy, Luxembourg, Netherlands, Poland, Sweden, Ukraine, but this last one is not an EU member State. Andorra, Armenia, Azerbaijan, Liechtenstein, Monaco, Russia, and the EU member States Austria, Belgium, Germany, Ireland, Malta, and United Kingdom have not ratified it yet.

Beside to the Convention of Human Rights and Biomedicine, one of the most relevant instruments protecting human rights in Europe is the Charter of fundamental rights of the European Union. It became binding as the Lisbon Treaty came into force⁵². Its first article is dedicated to protecting human dignity: the innovative contribution of this perspective concerns dignity as an essential part of a human being, recognizing it as due to every individual without discrimination. According to Article 3,⁵³ in the field of medicine and biology, the free and informed consent of the person

⁴⁹ Jehovah's Witnesses Of Moscow V. Russia, Eur. Ct. H. R., 10 June 2010, App. No. 302/02.

⁵⁰ In re T. (Adult: Refusal of Treatment) 3 Weekly Law Reports 782 (Court of Appeal); Newcastle Upon Tyne Hospitals Foundation Trust v LM [2014] EWHC 454 (COP) (26 February 2014).

⁵¹ Olivier De Schutter, *The Two Europes of Human Rights: the Emerging Division of Tasks between the Council of Europe and the European Union in Promoting Human Rights in Europe*, 14 Colum. J. Eur. L. 509, (2008); Elizabeth F. Defeis, *The European Union's Treaty of Lisbon and its Impact on National Politics and Policies: The Treaty of Lisbon and Accession of the European Union to the European Convention on Human Rights*, 18 ILSA J Int'l & Comp L 387 (2012).

⁵² Giuseppe Di Federico, *Fundamental Rights in the EU: Legal Pluralism and Multi-Level Protection After the Lisbon Treaty*, in THE EUROPEAN CHARTER OF FUNDAMENTAL RIGHTS: FROM DECLARATION TO BINDING INSTRUMENT, 38 (G. Di Federico, ed., 2011).

⁵³ It states the "Right to the integrity of the person 1. Everyone has the right to respect for his or her physical and

concerned, must be respected according to the procedures laid down by the law⁵⁴. It seems that in the EU Member States the protection of dignity and free consent to medical treatment of persons has two tools of protection: on the one hand by the Charter of Fundamental Rights of European Union, and on the other hand by the European Convention on Human Rights and Biomedicine. However, some UE and CoE Member States did not ratify the last one. The reasons of this policy choice could be connected to two different main reasons: on the one hand, cultural and religious roots of the specific Member State, such as in Austria, Germany⁵⁵, Italy, Ireland, Poland, Russia, Malta. For these countries, the Convention on Human Rights and Biomedicine could be viewed as too permissive and favourable towards interventions on the issue of protection of life and physical integrity, especially as regards the beginning and end of life, with specific reference to abortion and euthanasia. On the other hands, other Member States, such as United Kingdom and Netherland, according to their advanced policies in bioethical and biotechnology issues could see the European Convention on Human Rights and Biomedicine as too restrictive. In the EU law, the European Convention on Human Rights and Biomedicine had no significant influences⁵⁶.

6. The European Convention on Human Rights and Biomedicine in the European case law

The case law regarding the European Convention on Human Rights and Biomedicine is rare, even if the Convention is used by the European Court of Human Rights⁵⁷ and national judges as “interpretative tool”, even in Countries that did not ratify it.

The European Court of Human Rights referred to it as limit to discretionality of national authorities. In *Glass v. United Kingdom*⁵⁸, a case related to authorisation for medical treatment of a disabled child, the ECtHR stated:

mental integrity. 2. In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law, the prohibition of eugenic practices, in particular those aiming at the selection of persons, the prohibition on making the human body and its parts as such a source of financial gain, the prohibition of the reproductive cloning of human beings.”

⁵⁴ Jean McHale, *Fundamental Rights and Health Care*, in *HEALTH SYSTEMS GOVERNANCE IN EUROPE: THE ROLE OF EUROPEAN UNION LAW AND POLICY*, 300, (Elias Mossialos & Govin Permanad & Rita Baeten & Tamara. K. Hervey, eds. 2010); Paolo Zatti, *Rapporto medico - paziente e "integrità" della persona*, in *NGCC*, 403 (2008).

⁵⁵ Specifically some scholars observed in Germany “a specific repulsion reaction to the Nazi past, the German doctrine has some difficulty in accepting legal solutions that may be connotated with violation of human dignity, though most of the times it is an unjustified fear that only leads to unnecessary criminalization” (Vera L. Raposo & Eduardo Osuna, *European Convention of Human Rights and Biomedicine*, in *LEGAL AND FORENSIC MEDICINE*, 1046 (Roy G. Beran, 2003).

⁵⁶ Jean McHale, *supra*, note n. 54, 286.

⁵⁷ Case C-237/09, European Court of Justice, 3 June 2010, De Fruytier; Case C-377/98, Opinion of Advocate General Jacobs, 14 June 2001, Kingdom of the Netherlands.

⁵⁸ *Glass v United Kingdom*, Eur. Ct. H. R., (Application No 61827/00). Fourth Section, March 9 2004. In the same sense, *M.A.K. and R.K. v. The United Kingdom*, Eur. Ct. H. R., March 23th 2010, App. No. 45901/05, 40146/06.

The regulatory framework in the respondent State is firmly predicated on the duty to preserve the life of a patient, save in exceptional circumstances. Secondly, that same framework prioritises the requirement of parental consent and, save in emergency situations, requires doctors to seek the intervention of the courts in the event of parental objection. It would add that it does not consider that the regulatory framework in place in the United Kingdom is in any way inconsistent with the standards laid down in the Council of Europe's Convention on Human Rights and Biomedicine in the area of consent (...); nor does it accept the view that the many sources from which the rules, regulations and standards are derived only contribute to unpredictability and an excess of discretion in this area at the level of application.

This statement about the excessive discretion of the medical or legal operators, seems to be extendable from the case of children to the case of unable elderly people. In both situations patients could have impaired capacity to consent⁵⁹. In case of elderly people their vulnerability is likely to be loneliness, not rare in their conditions, and loss of mental clarity.

In cases of persons no longer capable, the European Convention on Human Rights and medicine has been interpreted rather narrowly by some courts, as in the case of a Court of the Czech Republic⁶⁰. Referring to Article 4⁶¹ and Article 5⁶², the Court stated that any medical intervention in the person's health field, including research, must be carried out in compliance with medical professional standards, and only following the condition that the patient gave his or her free and informed consent. A Spanish court made the same point in the matter of compulsory medical treatment⁶³.

In some Member States of the Council of Europe, there are legal provisions for the protection of incompetent patients, such as in France⁶⁴, Germany⁶⁵, Spain⁶⁶, Netherland⁶⁷ and Italy. The case-law analysed shows how sometimes courts are very pragmatic in opening procedures to protect or to provide for the hospitalization of the elderly in nursing homes appropriate to their condition,

⁵⁹ NUFFIELD COUNCIL ON BIOETHICS, *DEMENTIA, ETHICAL ISSUES*. 138 (2009).

⁶⁰ Nejvyšší soud, 30 May 2013, 30 Cdo 1144/2013.

⁶¹ Article 4 – Professional standards. Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

⁶² Article 5 – General rule [Consent]. An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

⁶³ Juzgado de Primera Instancia de Gijón, (Spain), 4 May 2012.

⁶⁴ Cour d'appel de Douai, (Fr.) 28 septembre 2012, 12/02573; Cour d'appel de Rennes, (Fr.) 15 octobre 2013, 13/00216; Cour d'appel de Rennes, (Fr.) 29 octobre 2013, 13/00637; Cour de cassation, civile, Chambre civile 1 (Fr), 6 octobre 2010, 09-12.358, Inédit.

⁶⁵ VG Stuttgart, (Ger.) 19.7.2011, 4 K 766/11; AG Nordenham, (Ger.) 20.03.2011, 9 XVII 8/00; Landgericht Kleve, (Ger.) 31.5.2010 4 T 77/10; Oberlandesgericht Düsseldorf, (Ger.) 13.12.2007, I-8 U 123/06.

⁶⁶ *Infra*, notes n. 75, 76 and 77.

⁶⁷ Gerechtshof 's-Gravenhage, (Neth.) 13.07.2011, BR1370; Gerechtshof Amsterdam (Neth.), 12.08.2013, GHAMS:2013:2267; Gerechtshof Amsterdam, (Neth.) 29.10.2012, 2012:BY1473.

without any mention to supranational sources. The Italian courts, however, tend to justify their decisions on the opening judicial process for the protection of the weak person, called “amministrazione di sostegno” (hereinafter ADS), a form of guardianship provided by law⁶⁸, just referring to the Convention on Human Rights and Biomedicine. For instance, an Italian court stated that the ADS has a role, established by the law, focused to the care of the person incapable to consent and, consequently, subjected to appropriate protective measures regarding both his or her assets and personal choices, especially related to the effective participation in the decision-making about the consent to medical treatment.⁶⁹ National rules, that prohibit health intervention against the will of the patient, should be coordinated with supranational rules, such as Article 6 of the Convention on Health and Biomedicine and Article 8 of European Convention on Human Rights, in order to allow, under specific conditions, the issuance by the ADS of the consent to medical treatment in the event of the silence of the interested incompetent person⁷⁰. This approach poses a very important issue, related to the limits of paternalism and the respect of the will of the individual. Since in Italy the Oviedo Convention is not formally ratified, so it has no effect of law, judges seem to use it in the decisions for justifying their cultural beliefs, rather than juridical opinions. In these sense, a Court stated that the ADS may be entitled to give consent to experimental treatment proposed by the physician, but he or she must indicate in detail what the therapy consists, and the potential risks involved to the patient's health. In fact, the consent obtained by the ADS from the court does not exonerate the physician from the obligation to verify that all other conditions laid down in articles 16⁷¹ and 17⁷² of the Convention on Human Rights and Biomedicine are

⁶⁸ L. 9 January 2004, n. 6 (It.).

⁶⁹ Tribunale di Palermo, (It.) 9 December 2009.

⁷⁰ Uff. indagini preliminari Torino, Ord., (It.) 16 January 2013; Trib. Reggio Emilia, Sent., (It.) 24 July 2012; Trib. Rimini, (It.) 30 September 2004

⁷¹ Article 16 – Protection of persons undergoing research. Research on a person may only be undertaken if all the following conditions are met: there is no alternative of comparable effectiveness to research on humans; the risks which may be incurred by that person are not disproportionate to the potential benefits of the research; the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability; the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection; the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

⁷² Article 17 – Protection of persons not able to consent to research. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met: the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled; the results of the research have the potential to produce real and direct benefit to his or her health; research of comparable effectiveness cannot be carried out on individuals capable of giving consent; the necessary authorisation provided for under Article 6 has been given specifically and in writing; and the person concerned does not object. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions: the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same

accomplished. In many other decisions the judges underline that Italian law has to be interpreted respecting the abovementioned principles⁷³. However, in other decisions, the Italian Supreme Court of Cassation, on the contrary, recognise the Convention on Human Rights and Biomedicine as instrument that impose the relevancy of the wishes of the persons not able to express their will⁷⁴.

Instead, in Spain, that fully ratified the Convention, the judicial authorization to shelter in protected structures for specific care cites the European Convention of Human Rights,⁷⁵ the Convention on the Rights of Persons with Disabilities⁷⁶, the Universal Declaration of Human Rights⁷⁷, but not the Oviedo Convention.

The European Convention on Human Rights and Biomedicine was greeted by scholars and institutions as an important tool for the protection of weak parties in scientific research and medical treatments. However, European and National courts did not enhance it either where it has come into force in national systems, nor as a persuasive tool for protecting elderly people. It seems that the same lawyers who are involved in the protection of older people are not so confident into the application of the Convention itself. Nevertheless, the Convention on Human Rights and Biomedicine could be useful under two aspects: on the one hand the protection of elderly persons in the event of consent for medical treatments, and on the other hand the protection of the elderly suffering from typical diseases of their age involved in scientific research.

The application of the European Convention on Human Rights and Biomedicine and the references to the case law concerning elderly patients is still far from achieving significant results. However, it is highly esteemed by scholars, institutions and operators, through which it could reach a significant improvement to be effective for a proper treatment of the elderly.

age category or afflicted with the same disease or disorder or having the same condition; the research entails only minimal risk and minimal burden for the individual concerned.

⁷³ Relating to Article 6.3: Trib. Termini Imerese Sent., (It.) 15 January 2007; Trib. Modena, Decr., (It.) 15 September 2004.

⁷⁴ Cass. civ. Sez. I, Sent., (It.) 20 December 2012, n. 23707; Trib. Terni, (It.) 22 October 2010.

⁷⁵ Audiencia Provincial Vigo, (Spain) 16 September 2011; Audiencia Provincial Madrid, (Spain) 27 December 2011; Ibidem, 27 May 2011; Ibidem, 31 May 2011; Ibidem, 22 July 2011.

⁷⁶ Audiencia Provincial Sevilla, (Spain) 29 June, 2012.

⁷⁷ Audiencia Provincial Madrid, (Spain) 27 May 2011; Ibidem, 31 May 2011; Ibidem 22 July 2011.