

Report

□ From bioethics to informed consent: analysis of international legislation and euthanasia rulings

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Bioethics^(a) (from the Greek *bios*, life and *ethikos*, theory of life) is a discipline that arose in response to the need to set ethical boundaries on the scope of the medical and biological sciences, which continue to evolve at lightening speed^(b). The idea behind this was to balance the application of medical science with fundamental human rights, assessing some of the latest medical processes and issues, such as organ transplantation, euthanasia and assisted fertilization, from an ethical perspective.

The Second World War highlighted the need to protect the fundamental rights of people in the medical and scientific world, and since then the development of molecular biology and genetic engineering techniques has made this an ever more pressing issue. As neither the Universal Declaration of Human Rights of 1948, nor the Rome Convention of 1950, nor even the International Covenants of 1966 provide protection for the specific human rights or the dignity of the human being in the face of the rapid development in the medical sciences, the Council of Europe drew up a specific Convention to this end, known as the Oviedo Convention^(c). Since then, the Convention has proved itself an indispensable tool for filling gaps in relevant international legislation. That being said, the Oviedo Convention merely limited itself to establishing general rules, which are considered

mandatory by signatory states, and more specific aspects of the subject are the province of other legal documents such as the Universal Declaration on the Human Genome and Human Rights^(d), the additional

^(a) The first definition of bioethics was given by Reich, in “*Encyclopedia of Bioethics*” in 1978. In this work bioethics was defined as the “systematic study of human behaviour in the area of bio-sciences and health care, when such conduct is examined in the light of values and moral principles”.

^(b) The first aberrant medical experiments on humans date back to the Nazi concentration camps. Pappworth MH. *Human Guinea pigs - here and now. Experimentation on man*. Routledge and Kegan, London (United Kingdom), 1967. Lifton RJ. *The nazi doctors: medical killing and the psychology of genocide*. Basic Books, New York (USA), 1986.

^(c) The *Oviedo Convention* (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. CETS No. 164) takes its name from the place where it was signed by the member states on April 4th, 1997. It entered into force on December 1st, 1999, after negotiations that lasted for more than five years. It is the most important international instrument for the protection of the human being with regard to biomedicine. The Convention consists of a preamble followed by fourteen chapters. It is possible to find information on the signatory states and their individual ratification details on the Council of Europe website: conventions.coe.int

^(d) The Declaration was adopted by the United Nations Educational, Scientific and Cultural Organization (UNESCO) on 11th November 1997.

Protocol dealing with the prohibition of cloning human beings, n. 168^(e) and the draft *Protocols dealing with human genetics and the transplantation of organs and tissues, and medical research on the human being*^(f). However, due to the rapid march of progress in the medical sciences, such legislation can quickly become out of date.

Among the many topics touched upon by bioethics, the principle of patient autonomy in relation to health care is one of the most interesting and the most studied, both in Italy and abroad. The expression “informed consent” prompted bioethicists to analyse a number of related issues, which range from a patient’s refusal of so-called “aggressive” medical treatment and their choice of which treatment to undergo to their “right to [hear] the truth” about their condition, prognosis and the treatment options available^(g).

Informed consent is internationally protected by Art. 5 of the “*Convention on Human Rights and Biomedicine*”^(h), which provided the European Community legislature an opportunity to deal with the issue, particularly in relation to health and transparency of relationships among professionals. One of the most problematic aspects of informed consent regards “supportive care”⁽ⁱ⁾, notably nutrition and hydration of patients in a vegetative state, in the event that their interruption will inevitably lead to death. The Oviedo Convention does not refer expressly to vegetative patients, but it does state that the will of the patient must be taken into due consideration.

This, however, does not extend, even in the case of a direct request, to allowing the interruption of treatment

that is keeping the patient alive. On this issue, the provisions of the Oviedo Convention are in line with the European Convention of Human Rights of 1950, which states in Article 5 that “no one shall be deprived of his life intentionally.” In addition, both recommendation n. 1418, dated 1999, on the protection of human rights and dignity of the terminally ill and dying, and the non-binding acts of the World Health Organization^(j) appear to be of the same opinion. Nevertheless, none of them give clear directions on informed consent as regards supportive care. That being said, the overall tone of the international legislation seems to propend towards treatment rather than against it, whatever the wishes of the patient. Take, for example, the Amsterdam Declaration (1994) on the promotion of patients’ rights in Europe, which decrees that when the doctor has to operate in an emergency situation and the patient is unable to express their consent or lack thereof, it must be taken as a given^(k).

After reviewing the international regulations, it seems appropriate to mention that, with regard to national legislation, the first states to issued a law on euthanasia and assisted suicide were Australia in 1995^(l) and the Netherlands in 2001^(m). The latter, after having passed a law in which euthanasia was permitted, faced an uprising of reactions from both public opinion and the Committee of the United Nations, which asked for clarification regarding the legalization of this practice, focusing especially on its paediatric applications⁽ⁿ⁾. In reference to the above, which directly opposes recommendation n. 1418 on the protection of human rights and dignity of the ter-

^(e) The Protocol was signed in Paris on 12th January 1998 and entered into force on 1st March 2001. At the present time it has not yet been ratified in Italy. The full name of the protocol is: “*Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings*”. Council of Europe Treaty Series (CETS) No. 168.

^(f) *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research*, CETS No. 195, was signed in Strasbourg on 25th January 2005 and entered into force on 1st September 2007.

^(g) Berlinguer G. *Bioetica quotidiana*. Giappichelli Editore, Turin (Italy), 2006.

^(h) The Convention art. 5 states that: “*any medical treatment can be performed only if the data subject has given his consent*”. The Convention (CETS No. 164) has not been ratified by Italy.

⁽ⁱ⁾ The aspects that cause the most problems are those related to how to behave in regard to patients who are in a vegetative state, consisting of the loss of self-consciousness. “Supportive care” may consist of feeding and hydration of the patient who is in such a state.

^(j) Art. 8, Recommendation 14418 “*urges States to identify the criteria for validity of advance directives of treatment (as well as the testimonies collected by third parties)*”.

^(k) This stands unless it is apparent from an earlier expression of will that the consent would have been denied. In the event that requires the consent of a legal representative and medical intervention is urgently needed, consent is presumed to exist where it is not possible to get it. Article 3 to paragraph 7 states that “*in all other situations where the patient is unable to give informed consent and where there is a legal representative designated by the patient for this purpose, appropriate measures should be taken to carry out a substitute decision-making process, which should take into account what is known and, as widely as possible, what can be assumed with regard to the patient’s wishes*”.

^(l) Australia adopted the *Rights of the Terminally Ill Act 1995* (Northern Territory), followed by the *Euthanasia Laws Act 1997*.

^(m) The Law of 12th April 2001, entered into force on April 1st, 2002

⁽ⁿ⁾ See the *Committee for Human Rights*, UN Doc CCPR/C/NET/4 of 30th July 2008, at par. 38 et seq.

minally ill and the dying (1999), even the intervention of the Parliamentary Assembly of the Council of Europe has been in vain. The Assembly, in the light of what had happened in the Netherlands, had filed a motion in which they expressed the need for a more precise and detailed rules on the subject, but so far no such clarification has been forthcoming.

Among the European countries that have their own legislation on euthanasia and assisted suicide, Germany is definitely one of those that deserve more attention. Following a court case, similar in content to that played out in Italy that revolved around Eluana Englaro, a car accident victim in a vegetative state whose father was eventually granted the legal right to have her feeding tube removed in line with her previously expressed wishes, Germany has also found itself having to decide on euthanasia⁽⁹⁾. The BundesGerichtsHof (BGH), without mentioning either the Oviedo Convention or the European Convention on Human Rights⁽⁹⁾, drew up some internal rules *ad hoc*⁽⁹⁾ stating that they will protect the autonomy and desires of patients, if expressed, over matters arising from the aggravation of their state of health.

Leaving aside for a moment the guidelines and choices in legislative matters adopted by individual states, the European Court of Human Rights has constantly monitored the protection of human rights, with particular focus on ensuring respect for the right to life. The first ruling on the European Convention on Human Rights as regards euthanasia dates back to 1999 and concerns a Spanish quadriplegic, Ramón Sampredo, who fought for his right to assisted suicide for almost 3 decades⁽⁷⁾. His wish was not legally granted, but he did find an ingenious means of putting it into practice without exposing those who assisted

him to a risk of prosecution. This case has since been followed by many others, including the well-known judgment *Pretty v. United Kingdom*, which clarifies the position of the European Court, which gives importance to the principle of consent in terms of self-care, but will leave the decision of whether to allow or prohibit passive euthanasia to the single Member States⁽⁸⁾.

However, examination of the rulings in euthanasia cases reveals a tendency in the international arena to greater protection of individual autonomy than is reflected in the standards of informed consent and respect the right to life and related rights in rulings under the European Convention on Human Rights. The right to life is the most valuable asset to be protected, but this is inextricably linked with the respect for human dignity, an essential value worthy of protection above and beyond the collective and individual interests of others⁽¹⁾.

⁽⁹⁾ The ruling issued by Bundesgerichtshof is dated 25th June 2010.

⁽⁸⁾ The Oviedo Convention was not mentioned in the judgment because it had not been signed by Germany at the time.

⁽⁷⁾ This is the third law for the amendment of the rules of the fiduciary relationship (*Drittes Gesetz zur Änderung des Betreuungsrechts*) of 29 July 2009, which introduced living wills into German legislation, par. 1901 and 1901 b.

⁽⁶⁾ Ramón Sampredo, a Spanish fisherman and writer, became a quadriplegic at the age of 25, following a diving accident, and fought for his right to an assisted suicide for the next 29 years (en.wikipedia.org/wiki/Ramón_Sampedro).

⁽⁵⁾ Decision justified by restrictions necessary to protect the collective interests (art. 8, para. 2 European Convention on Human Rights: ECHR).

⁽¹⁾ The Oviedo Convention, entitles people to “*the dignity of the human being with regard to the applications of medicine...*”, aims to “protect the human being in his dignity,” former. article 1.

