

# Assisted suicide and new issues: the Ethics Committees

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**Abstract.** The recent reform of the organization of Ethics Committees in Italy is linked with the complex issue of end-of-life decisions. Starting from a reconstruction of the history and purpose of Ethics Committees, the article aims to provide an overview of the legislation and its evolution, and to highlight some questions that have not yet been fully answered in relation to assisted suicide. The confrontation with the dimension of suffering and pain represents one of the most problematic and still unresolved moral issues of the health and care professions. In this context, the creation of an Ethical Space, as an expression of a “medicine of proximity”, can be a valuable tool not only to find difficult answers to situations of severe suffering, but also to offer a comprehensive and supportive accompaniment to the person who asks to leave life, as well a concrete support to the health professionals involved in procedures to end-of-life, testifying a broad and active solidarity.

**Key words:** Ethics Committees; assisted suicide; aiding suicide; right to die; vulnerability; end of life; Italian Constitutional Court; Marco Cappato; Fabiano Antoniani

## Introduction: to the origins of Ethics Committees

Toward the end of the 1960s, the development of a philosophical and cultural movement focused on concrete moral problems was an important factor in the emergence of the discipline that one of its founding fathers, Potter, named ‘bioethics’ Before this time, the field of inquiry of academic philosophical ethics, at least in the Anglo-Saxon cultural area, was almost exclusively focused on analytical metaethics (1).

The profound cultural change that followed the transformation of roles and relationships in the family sphere, and the unprecedented possibilities offered by science in the areas of sexuality, reproduction, and life extension beyond the limits set by nature, drew attention to the phenomenon of bioethics, even outside professional circles.

Apart from the evolution of bioethics towards a medical ethics, in contrast to the original approach oriented toward an ethics of “the whole living”, an important aspect that has emerged since its beginnings

is the interdisciplinary and pluralistic approach to the various issues (2, 3).

The forerunner of what are now known as Ethics Committees, was, probably, the ‘Admissions and Policies Committee of the Seattle Artificial Kidney Center at Swedish Hospital’, established in 1962 at Seattle Hospital to decide on the order of priority in access to hemodialysis services for patients with chronic renal failure (4).

By this time, the term ‘bioethics’ had come into prominence through the German Protestant pastor Fritz Jahr, who proposed to extend the Kantian categorical imperative beyond the anthropic sphere (1927), but bioethics as a discipline had not yet been born. The Canadian hospital, however, was at the center of a crucial ethical issue concerning the allocation of resources resulting from the reduced availability of beds and the consequent need to limit the free provision of dialysis treatment to only 17 outpatients compared to the number of patients eligible for the same treatment.

In all its drama, the bioethical problem of re-

source allocation, recently revived by the entire world community with the Covid pandemic emerged: "Who will live if not all can live?" (5, 6, 7). Moreover, access to dialysis was paradigmatic of all other situations in which choices had to be made in the face of limited resources.

The Canadian hospital decided to establish a special committee with the task of defining the criteria for admission to dialysis. This committee was the first hospital ethics committee in the history of medicine.

The composition of the committee was an initial aspect of the discussion, which was closely followed by the related issue of defining morally acceptable and perceived just criteria for the so-called 'tragic' decisions.

The seven members of the so-called 'God Committee' were: a housewife, a minister, a banker, a labor leader, a government official, a lawyer, and a surgeon appointed by the King County Medical Society (8).

Almost all the members, whose identities were kept absolutely secret, were for the most part totally unfamiliar with the scientific and technical dimensions of the problem. They themselves never knew the identities of patients admitted to dialysis or excluded and died of renal failure. Only once did the Committee meet a patient face-to-face.

A decision that was supposed to be based on strictly clinical parameters was delegated to non-physicians who applied extra-clinical, somewhat questionable criteria aimed at measuring the value of human life: candidates for dialysis had to reside in the state of Washington, be under 45 years old, and be able to pay or be paid for treatment (9).

R. Fox and J.P. Swazey wrote: "A person worth having his or her life saved by an expensive and rare medical treatment such as chronic dialysis must be one who is considered decent and responsible. A history of social deviance, such as incarceration, or evidence that a person's married life was not intact or free of scandal were strong contraindications to selection. The preferred candidate was one who had demonstrated commitment to work and success in his or her career, who attended church and clubs, and who actively participated in community affairs (10).

However, since these criteria were not sufficient to identify a small number of suitable, another, no

less controversial list of criteria and requirements was established. Candidates had to: be employed, have a certain level of education, complete a project that had been started, be indispensable to others who depended on him, have a family that could support him, and other more or less arbitrary criteria.

In the 1970s, with the spread of hemodialysis, this committee was finally disbanded.

Given the criticality of many factors, this committee called public attention to the need for a broader, multidisciplinary view of the ethical implications of everyday and experimental medical practice.

This collegiality and pluralism-based approach to medical decisions spreads and soon the establishment of BioEthics Committees, whose composition and criteria for decision-making were progressively more carefully defined, became a common clinical practice as part of a shared decision-making process between health-care and medical institutions.

In 1976, in the case of Karen Quinlan, a young 21-year-old woman who had been in a vegetative state for 10 years and for whom her adoptive parents repeatedly requested euthanasia, the new jersey State Supreme Court for the first time assigned the Bioethics Committee an advisory role in decisions to suspend medical interventions deemed burdensome and futile in patients with severe brain damage who were unable to consent (11).

## **Past and future of Ethics Committees in Italy**

From the United States, the committees then gradually spread to many other countries, also because of the European Guidelines for Good Clinical Experimental Practice, which explicitly entrusted these committees with the task of reviewing research protocols to provide the public with guarantees of respect for the moral rights and well-being of those participating in a medical trial.

The Italian legislation recently updated based on the EU Regulation and confirming the previous legislation (Ministerial Decree of February 8, 2013), states that Ethics Committees are independent bodies with the task of ensuring the protection of the rights, safety, and well-being of subjects participating in trials and

guaranteeing this protection to the public (Art. 1 paragraph 2 and Art. 4 paragraph 1 Ministerial Decree 2023). According to paragraph 3 of Art. 1 of Ministerial Decree 2023, Ethics Committees ‘may exercise (...) advisory functions on ethical issues related to clinical research and care activities, with the aim of protecting and promoting the values of the person, to the extent that they are not already assigned to specific bodies’. The same legislation also provides that “... Where not already attributed to specific bodies, Ethics Committees may also perform advisory functions on ethical issues related to scientific and care activities, with the aim of protecting the values of the person (...)” (art.1.2).

Currently, in Italy, in accordance with the provisions of EU Regulation 536/2014, a deep revision process of ECs is underway. In fact, Law No. 3 of 2018 (“Delegation to the Government on clinical trials of medicinal products as well as provisions for the reorganization of the health professions and on the Health Administration of the Ministry of Health”) provides, not only for the establishment of the “National Coordination Center of the Territorial Ethics Committees for Clinical Trials of Medicinal Products for Human Use and Medical Devices (CCNCE)” at AIFA, but also for a decisive reduction of territorial CEs to a number of 40 compared to the 90 currently operating on the national territory.

This is a significant and important restructuring that will profoundly change the current structure of territorial CEs deciding on trials of medicinal products and medical devices.

In Italy, the National Bioethics Committee (NBC) already recommended in 2001 that a distinction be made between the areas work of the ethics committee responsible for evaluating and monitoring pharmacological and biomedical research and those that help with clinical practice, healthcare training issues (12).

Some Italian regions (Veneto, Tuscany, Friuli-Venezia Giulia, the Autonomous Provinces of Trento and Bolzano, and Emilia-Romagna) have taken this indication and established these bodies in healthcare institution through a regional law.

The role and competence of Ethics Committees, moreover, have recently been the subject of extensive

debate, following the Constitutional Court’s decision No. 242 of September 25, 2019, which reopened the debate in Italy on the controversial issue of the criminal liability of assisted suicide for people who are already determined to take their own lives, in the name of the right to die with dignity (13, 14).

The ruling related to the case of Italian parliamentarian Marco Cappato, who was charged with the crime of assisted suicide for having accompanied FABIANO ANTONIANI to a Swiss clinic in February 2017 to enable him to carry out his intention to end his suffering after a serious road accident that had left him blind and quadriplegic.

This decision matured over time in the face of the painful living conditions described by ANTONIANI himself, which were marked by suffering and despair.

In its judgment, the Constitutional Court amended Article 580 of the Italian Criminal Code, which refers to aiding and abetting suicide, in the part that does not exclude the criminal liability of a person who facilitates the execution a person’s suicidal intent under the specific conditions mentioned in the ruling. In this context, the Court has established a series of requirements aimed at avoiding any abuse and ensuring the protection of the person requesting assistance in dying and, as well the protection of particular situations of fragility (patients suffering from an incurable disease that causes them severe and subjectively intolerable pain and distress, and who are kept alive by life-sustaining treatments, but (iv) retain full mental capacity).

The decision, which calls on Parliament to approve a detailed regulation of the matter, takes a stand on a controversial issue of assisted suicide for patients suffering from incurable diseases that has specific characteristics compared to suicide tout court.

In both cases, there is a desire to escape from living conditions marked by suffering by deciding to end one’s existence. However, assisted suicide is related to the development of new biomedical technologies that make by many years the lives of incurable patients suffering from seriously disabling diseases whose suffering cannot always be sufficiently alleviated by medication. Assisted suicide refers to the act of performing suicide by self-administration of a lethal medication with the assistance of a physician (PAS, physician assisted suicide) whose role is generally limited to the prescription

of the drug or another healthcare provider.

In the case of suicide, on the other hand, the person wishes to escape an existential and/or social distress, not always related to a medical condition, by choosing for himself the means of giving himself death and autonomously departing.

In both cases, there are decisions that involve sensitive and painful aspects that must always be treated with respect, since they concern a set of values that touch the innermost core of the person.

On the ethical level, very opposite positions have been facing each other for years.

Subjectivist ethics, which denies the existence and recognizability of universal objective values, holds that life is a subjective good and that only the individual can judge and decide the value or disvalue of his or her own life in the various conditions of existence, health or disease (15, 16). In this view, which values the free choice of the competent and appropriately empowered person, the duty to treat oneself is not ethically justified; on the contrary, there is an individual right to refuse treatment even if it is life-saving and even to demand to die prematurely.

Personalist ethics, accepting the idea of the objective value of life and the constitutive relationality that characterizes social life, denies that freedom can be expressed absolutely, considers life as an unavailable good that also has a social value, and consequently, denies the right to die, and affirms the duty to live (17).

In the background is Law 219/2017 (Regulations on informed consent and preventive treatment provisions), which is the result of a long and tormented mediation between views that privilege the dignity and responsibility of the human person regarding relation to his or her own health and the health of others, and view that value individual self-determination.

The law expressly permits the refusal or withholding any treatment, including life sustaining one, accepting the distinction between causing death and allowing the illness to progress.

In particular, the law explicitly provides for the abandonment of artificial nutrition, which has been the subject of moral and legal controversy for years, and implicitly provides the renunciation of intubation (18).

With the 2019 “Cappato/Antoniani” ruling, the

Italian Court expands the limits of individual self-termination, by going beyond the simple right to refuse or discontinue medical treatments as explicitly provided by Italian Law No. 219 of 2017) to legalize assisted suicide in the presence of well described conditions.

The review of the conditions that legitimate is entrusted by the Court to the public structures of the National Health Service, which must review the relevant modalities of execution, which must be such as to avoid abuse to the detriment of vulnerable persons, to ensure the dignity of the patient, and to prevent the patient from suffering.

For this review, which is necessarily clinical in nature, the Italian Court, recalling the ‘delicacy’ of the decisions, provides for prior assessment by ‘a third collegiate body’ ensure the protection of particularly vulnerable situations. Pending the intervention of the legislator, the Constitutional Court entrusts this task to the competent territorial Ethics Committees, which are already endowed with an advisory function to ensure the protection of the rights of the person in clinical trials.

### Critical issues

The Court’s reference to Ethics Committees, is certainly an important fact for the appreciation of these committees, which unfortunately are not always given due credit.

However, this decision has raised some critical questions. While these committees have the advantage of being spread throughout the country, they also have the disadvantages of being mainly responsible for the scientific and ethic-legal evaluation of clinical trials, and only in exceptional and residual cases do they perform other advisory tasks on emerging problems in clinical practice. For this reason, as envisaged in the reference legislation, these committees are composed of experts dealing with clinical and biomedical research and rarely of experts dealing instead with ethical issue of palliative care, end-of-life care and clinical-assistance.

Although the legislation provides that these committees may also express themselves on ‘problems of an ethical nature in health practice’, in relation to issues

related to medical and care activities, in order to protect and promote the values and rights of patients, the situation described by Consulta certainly represents a new and completely different dimension from that in which the current committees actually operate.

The possibility of providing for other specific professional competencies, in addition to the current expertise (anesthesiologist, palliative care physician, neurologist, psychologist and a representative of the nursing professions) does not seem appropriate in view of the specific purpose assigned by the Constitutional Court, namely “to ensure the protection of particularly vulnerable situations”, which requires expertise to assess requirements that are ethical rather than clinical in nature.

Furthermore, because there are no viable treatment alternatives in both circumstances, there can be no confusion about the Court’s comparison between the request for assisted suicide and the evaluation of the so-called compassionate use of medications. In contrast to assisted suicide, where death is requested in the abandonment of hope, compassionate use involves evaluating the use of drugs that have not yet been validated or are in the process of being validated, as well as those for which there is a rationale and there is preclinical scientific evidence (19).

Another issue is the planned reduction of the number of these Committees, which runs the danger of making the evaluation of the doctor-patient interaction in suicide assistance and the proper defence of the rights of the extremely frail patient ineffective.

A second option is to entrust the evaluation of such decisions to the ‘committees for ethics in clinical practice’, operating in various regional realities with a more streamlined composition and at the same time with a qualification in the specific field of bioethics and bio-law, which could provide a response from the public structures approached as close to the citizen as possible.

In this regard, it is important to note that the National Bioethics Committee (NBC) had previously expressed the need to create by law a Clinical Ethics Committee with distinct functions, roles and modalities from the Ethics Committees for pharmacological trials throughout the national territory. This opinion was issued on March 31, 2017. These committees

would, in particular, “analyze and discuss the nature of the moral problems that patient care and therapeutic practice can present in the most delicate situations (such as the beginning and end of life), with vulnerable subjects (such as minors, the incapacitated, the elderly, and immigrants), in the management of incidental findings; to propose and supervise institutional bioethics training activities; to take care, when possible, of the bioethical awareness of citizens” (20).

The document specifically highlights the need to make provision for a different composition with specific bioethical and biojuridical competencies, which would differ from the current territorial committees in charge of evaluating trials, in order to provide different competences and functions for the drafting of consultation opinions for doctors and patients in relation to specific clinical cases (not mandatory, as in the case of trials).

However, these committees, which are currently not even registered in the various geographical areas operate in a sporadic and non-homogeneous way.

These elements could lead to delays, the risk of contradictory pronouncements throughout the country and the consequent possible ‘migration’ of sufferers to more ‘open’ committees. Another problem relates to the more consultative than decision-making function of these committees, which were set up with a predominantly assistance function towards health professionals in dealing with ethical dilemmas.

If, therefore, the ruling has the merit of reinforcing the role of Ethics Committees, ignored and not mentioned in Law 219/2017, great efforts are still needed for their real and concrete development.

Following the Court’s ruling in 2019, the Marche Ethics Committee (MEC) was, for the first time, called upon by the Court of Ancona to verify the existence of the conditions set by the Italian Constitutional Court in order to authorize the assisted suicide of a young man remained tetraplegic due to cortical damage.

The procedure had been initiated only after a tormented judicial affair with an initial sentence to the contrary by the Court of Ancona (26.03. 2021), and a subsequent order that overturned the previous decision, requiring the Marche Region Health Authority to verify whether the conditions for access to assisted suicide were met and to ascertain whether the chosen

method, method and drug were suitable for guaranteeing him the most rapid, painless and dignified death possible.

MEC considered that, in the case submitted to it, all the requirements were met. In order to carry out this assessment, MEC used the following professional figures: a palliative physician, a neurologist with expertise in the pathology from which the applicant was suffering, a psychiatrist, a psychologist, an anaesthetist-resuscitator, a forensic scientist, and a nurse with expertise in integrated home care. However, this procedure has been severely delayed in connection also with the need to identify the method, quantity, and manner of administering the lethal drug, which has resulted in prolonged suffering and calls for legislation that cannot be postponed.

### **The operational possibilities of an Ethical Space**

To give an answer to the person who asks to be allowed to die or to be assisted to die is undoubtedly one of the most difficult tasks. The question of how to deal with the dimension of suffering and pain is, moreover, one of the most controversial moral issues in the health and care professions. In absolute agreement with the precise terms of the Consulta, it is considered that medical treatment should not end with the mere administration of a lethal drug, even if this is preceded by strict adherence to rigorous clinical conditions. Such an approach would indeed be disrespectful both to the suffering of those who ask for help in ending a life marked by pain and to those who are called upon to approach that suffering in order to assist in responding to such a request.

Indeed, without prejudice to absolute respect for the free and responsible will of the person, it is understood that, in any case, the possible responses must be aimed at assisting the suffering person to deal with the pain and suffering, to recognise, accept and care for the needs of the other. The need to 'care' suggests that one must not stop at the fulfilment of one's professional duty, but always calls for an openness to listening to the other in order to facilitate an understanding that is as close as possible to the needs of the suffering person, also through an interpretive work of

behaviours, signs and 'unspoken' that could hide important requests for help. In this context, the activity of the Ethical Space can witness and build a medicine of closeness that is close to the person, to the families and also to the operators in all moments of life, even in the most delicate phases of the end of life. We remember that proximity, the key word of the territorial care reform project, is not only expressed in terms of structures, but implies (even more) listening, meeting, accompanying, removing obstacles, sharing.

In this context, the Ethical Space, an institution that has existed in France for decades and described by the CNB in its recent opinion of 2021, dedicated precisely to vulnerability, can be an important tool to respond to fragility, express it and protect it with actions and support that go beyond the purely clinical dimension (21). A place where the concrete bio-psycho-social situation can be assessed and a care network can be established that responds not only to the clinical but also to the emotional and existential needs of the person, respecting his or her cultural and social background and diversity. The Ethical Space, always in accordance with the wishes of the person and in collaboration with the competent bodies CE, could promote actions of listening, dialogue, support and encounter that do not aim to hinder a responsible will to make decisions at the end of life, but, as the Council stresses, to ensure the protection and support of particularly vulnerable situations.

The motivations that lead the sick to ask for assistance in dying are many: pain, anxiety, loneliness, fear, depression, loss of hope, the feeling of having lost one's dignity, of having no control over one's life, the feeling of being a burden to others, the need for social support.

Therefore, precisely in view of the task established by the Italian Constitutional Court to protect frailty, it is important to be able to carry out a calm analysis that aims - free from prejudice and ideological bias - to eliminate all possible causes that could lead the person to a decision that is not entirely authentic, and to decipher all requests for other assistance and to circulate all resources so that no one feels excluded from social and health care. However, it must also be emphasised that this intervention must not become a persuasive operation aimed at influencing the free decision of the person concerned.

## Conclusion

The possibility of implementing this initiative in the context of healthcare thus represents an important opportunity to explicitly welcome and acknowledge the vulnerability not only of those being cared for, but also of all interlocutors involved in a procedure that undoubtedly has profound emotional, psychological and existential implications and implication, testifying to a broad and active solidarity. To approach, understand, accept and process the pain of those who can no longer bear a life of suffering, and of those who, as health professionals, are called upon to approach suffering, is to prevent it from getting out of hand, and instead to open up the possibility of finding appropriate responses, if not at the therapeutic level, then at the relational and human one.

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