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Original article

End-of-life in the operational functioning of public healthcare: ethical and legal issues

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Abstract. *Background and aim:* The article aims to outline the current scenario relative to the medical role in end-of-life issues. In order to do this, historical-legal references have been drawn upon relating to technical, legal and scientific thought and doctrine, as it has come down to us in the medical field through the evolution of ethical and philosophical frameworks. *Methods:* The authors have conducted a thorough analysis of end-of-life legislative initiatives, in Italy and across the EU, and court rulings to outline possible ways to harmonize and reconcile the current medical ethics frameworks with the needs and rights of all, especially the most vulnerable among us. To that end, the necessary operational choices and adjustments have not yet been made by our legal system, from a technical, as well as moral, standpoint. *Results:* An operational proposal has therefore been laid out to protect both healthcare providers and patients, in a relationship that goes beyond treatment in the strict sense, which prioritizes mutual needs as an integral part of a common, essential path. *Conclusions*: In order for doctors to consider themselves complete, they should in fact deal not only with life, but also with death. It is incumbent upon legislators to take responsibility for governing such evolving forms of end-of life care. (www.actabiomedica.it)

Key words: end-of-life ethics, medical assistance in dying, ethical decision-making, euthanasia

Introduction

Addressing end of life issues inevitably gives rise to deep concerns and ethical quandaries, related not only to the complexity of the arguments addressed, to the tension that is created between opposing interests as important as life and self-determination and to the difficulty of finding a reasonable balance between them. Above all, however, we need to deal with the inability to identify the basic cultural guidelines through which to interpret and deal with such issues. In other words, what is missing is not only a harmonized and widely shared vision of the relationship between human beings and their own death, but, more generally, a frame of reference centered around the prerogatives that must exist between individuals and society, above all in consideration of the State's regulatory function needed when certain individual actions inevitably result in damage, even if limited exclusively to the doer of such actions. While on the one hand the objective of protecting life remains firm, on the other hand the recognition of spaces for man's freedom of self-determination is increasingly consolidating (1). The debates and reflections on death as a "life choice" therefore pose a question that has always divided the supporters of the ethical-philosophical vision from the supporters of the secular vision: does prolonging an existence from a merely biological standpoint really

mean protecting the life and the dignity of the human being? On 4 April 1997, Italy adhered to the "Convention for the protection of human rights and the dignity of the human being with regard to the applications of biology and medicine" (2), known as the Oviedo Convention, a fundamental milestone for the legislative governance of bioethics in healthcare.

The Convention was inspired by the 1948 Universal Declaration of Human Rights (3), based on the awareness that the "rapid developments in biology and medicine" could "endanger human dignity from improper use" of such innovations. Hence, the consequent "need to respect the human being both as an individual and in his belonging to the human species, recognizing the importance of ensuring his dignity". Certainly, at the time medical resuscitation and surgical procedures were still in their infancy, as was knowledge of oncology, including the role of viruses in the etiopathogenesis of many diseases and tumors (4), kidney transplants (5) and whatnot; therefore, there was no mention of viral infections in kidney transplants (6). In 1998, the Code of Medical Ethics also complied with the principles dictated by the Oviedo Convention, establishing, among other things, that "the doctor must refrain from futile care from which no benefit can reasonably be expected for the health of the patient and/or an improvement in the quality of life" (7-9). However, while in the rest of the world the right of each individual self-determination was proclaimed with regard to what health treatments to undergo in anticipation of a subsequent loss of the ability to understand and decide, in Italy no specific law allowed for any advance directives to be legally binding.

End of life: between bioethics and biolaw

The progress of biomedical and biotechnological knowledge has been matched by the unstoppable advance not only of a secular culture on the crucial issues inherent in beginning of life (i.e. scientific advances affecting the very core principles of human life still to be born, such as embryo research or even controversial childbirth procedures) (10-14) and end of life, but also by growing social sensitivity about issues related to the dignity of living and dying, inevitably originating new "instances of justice" and, consequently, the transposition of bio-ethics into biolaw. Hence, biolaw, i.e. the set of procedures and norms in which the legal response to bioethical questions is implemented, becomes instrumental in outlining the legal standards governing life sciences and healthcare. If on the one hand the underlying issue relative to requests for assistance in dying by patients in a state of suffering or terminally ill is a highly sensitive issue in modern societies, it also appears to be extremely complex in the legal realm. The debate is centered around conflicting conceptions of life and its availability: the secular one, based on the theory of the availability of life, and the religious one, rooted in the sacredness of life which, as the ultimate gift, is to be viewed as an asset available to humans, but without any form of "ownership". The need to govern such instances via legislative means is ever more pressing, due to the growing availability and evolution of innovative medical techniques in the terminal stages of the patients' lives. The high technological standards achieved in medical care and research, which make it possible to avoid immediate death, both for diseases with a strong degenerative effect and for particularly severe physical injuries, have resulted in more and more cases of individuals afflicted with particularly serious conditions being kept alive artificially, or even in "conditions of suspended death" (coma or permanent vegetative state) (15), thus generating the "fear of not being able to die, of being kept alive as a shell of himself" (16). When life is sustained artificially, making decisions as to to the use of medical devices and duration limits is extremely complex; such daunting difficulties inevitably lead to doubts and uncertainties that in other historical times were unimaginable, and where therefore the law had no way of operating, but is now called upon to provide standards for the protection of all.

End of life care: an overview of the European state of affairs

The legal landscape on end-of-life choices appears quite varied in Europe, with a clear trend towards a substantial opening, especially compared to Italy, to the legal recognition of advance treatment

directives and a widespread distrust, with few exceptions, towards active euthanasia (17). Although passive euthanasia seems to find legal recognition in most legal systems, no such conditions seem to exist for a similar level of recognition of active euthanasia. This is confirmed by the general tendency to keep active euthanasia illegal, hence with no specific regulatory norms. Two important exceptions do stand out however, which may portend to the possible legislative evolution in other European legal systems: Holland and Belgium differ from other countries in that they have specific legislation allowing for active euthanasia. In the process towards legalisation, the Netherlands was the first in Europe to put in place legislative standards for such practices, partly due to a social context which is particularly sensitive to the issue and has already been largely in favor of liberalization for some time. From 1991 onwards, and, in particular, with the law on Burial and Cremation of 1994 (18), the legislator intervened by incorporating the indications of the jurisprudence, arranging some administrative procedures which, in substance, allowed the doctor, who had practiced euthanasia or assisted suicide, to avoid prosecution if he had met certain adequacy criteria and had written a report on the patient's causes of death.

On the other hand, the law on the termination of life upon request and on assisted suicide dates back to 2002 which, through the introduction of a specific exempt in the penal code, expressly legalizes such acts if carried out in compliance with certain procedures and adequacy criteria. The adequacy criteria are therefore established by law and no longer entrusted only to judicial evaluation. In order for the doctor's action to be lawful, the law requires, first of all, the prior assessment of the soundness of the patient's request and of their condition of intolerable physical suffering; then come the provision of information to the patient about their situation and prospects, the assessment of the lack of alternatives in light of their clinical conditions, the consultation with another independent doctor, who has to examine the patient and draft an opinion on whether such requirements were met and, finally, professional assistance in ending the patient's life. The law also regulates advance directives (18,19), which have the same value recognized to the request for assisted suicide in the present. Parental involvement is required for minors who request euthanasia or assisted suicide (20). The Dutch model was followed by Belgium, the second European country to have legalized euthanasia.

After an in-depth debate, in 2002 the "Loi relative à l'euthanasie" was in fact approved, a law which authorizes euthanasia if it is practiced on the basis of certain conditions and in compliance with certain procedures indicated by the law itself (20,21). Doctors are required to ascertain that their patients are in a condition of serious and incurable disease, involving intolerable physical or mental suffering that cannot be allayed in any way; moreover, the request for euthanasia, necessarily in written form, must be demonstrably "voluntary, carefully weighed and reiterated", and never come as a result of "external pressure", and made by a patient of legal age and mentally competent. The doctor is then required to inform the patient about the remaining prospects regarding his health and about any further treatment options, even of palliative nature, and must conclude that no reasonable solutions are left with respect to the patient's illness, and lastly that the suffering is persistent and the patient's will to die has been reiterated. The consultation of another independent doctor is also required, who is charged with evaluating the severity of the patient's conditions and filing an official report. It should be noted that the law guarantees the doctor's freedom of conscience and provides that the anticipated or current request for euthanasia is not binding.

Belgian law (22), in addition establishing stricter and detailed governance of some aspects neglected by Dutch law, deviates, in some respects, from the latter's pragmatic approach because it expresses a conception of the value of life which enhances the qualitative aspect and its disposability by the subject, thus mirroring the predominant vision in common law systems, but also represents a bold legislative choice made through the compromise between the various sentiments and deeply-held beliefs emerging from the social and parliamentary debate, thus reflecting the high degree of diversity in Belgian society (22).

Those two legislative interventions undoubtedly offer a valid example of how a law can deal directly, and without prejudice, with a delicate issue such as that of euthanasia, moreover without necessarily entering

into the merits of the choices that are up only to the individual, but rather the conditions for respecting the patient's will in relation to his real situation, through a discipline mainly based on the evaluation of the concrete case. For this reason they represent a very advanced and thought-provoking legislative solution in the European context, for legal systems striving to safeguard the central role and worth of each human being, along with the principle of pluralism and diversity, when providing legal validation to a widespread phenomenon (23).

A succinct overview of currently in force end-of-life pieces of legislation in other major European countries has been outlined in Table 1

End of life in Italy - Law 219/2017 and the intervention of the constitutional court with ordinance n. 207/2018 and ruling n. 242/2019

The Italian legal system upholds the principle of non-disposability of human life, by virtue of the provisions of Articles 5 of the Civil Code (37), which prohibits any act aimed at disposing of one's body such as to cause permanent damage, and of Articles 575, 576, 577, 579 and 580 of the Criminal Code (38), which punish consensual homicide and assisted suicide. Such a stance however was partly modified by Law no. 219/2017 (39) on "informed consent" and "advance treatment directives" (DAT), which recognizes the patient's decision-making autonomy and, in the context of the relationship of care and trust between doctor and patient, the prerogative of the latter to refuse or withdraw medical treatment, even life-saving forms, in the face of a conscious and informed will (40); such an end-of-life path involves palliative care, including deep and continuous sedation (40,41). Furthermore, the legal value of advance treatment directives has also been acknowledged, by virtue of the possible future inability of patients to exercise their right to self-determination. Law 219/2017, therefore, does not legitimize euthanasia or assisted suicide, but rather marks a clear ethical and legal differentiation between such interventions and the refusal of treatment or the request to withdraw it. The Italian legal system has over the years proven extremely rigorous towards euthanasia or assisted suicide, criminally punishable conducts pursuant to art. 575 (first-degree murder), art. 579 (consensual homicide) and art. 580 (incitement to suicide or assisted suicide) of Italian criminal statutes. The red line between the two different criminal profiles, as outlined in Article 579 and Article 580 (42), lies in the ultimate cause of death arising from a third party, i.e. by the patient. It is worth noting that in such a specific case, current jurisprudence has not been consistent in defining to what extent the facilitation of suicide should be viewed as an act of instigation. Also unclear is whether or not a constitutionally oriented interpretation of the law may limit the conduct punishable to cases in which assisted suicide has substantially influenced the patient's will to commit suicide, by providing an incentive through collaboration (43). It is on this very legislative framework that the Marco Cappato trial was based, for the assistance in suicide provided to Fabiano Antoniani (also known as DJ Fabo) at a specialized Swiss clinic. Such a trial ended with the Milan court, through Ordinance 207/2018 (44), raising the question of constitutional legitimacy of Art. 580 of the Italian Criminal Code. Specifically, the Milan judges took issue with said article (a) "in the part where it criminalizes assisted suicide as an alternative to instigation and, therefore, regardless of the contribution to the determination of (or the possible contribution to) the suicidal intent"; and secondly (b) "in the part where it does not differentiate between conducts of simple facilitation and those of instigation when determining punishment". Both the Constitutional Court Ordinance n. 207/2018 (44) and its ruling n. 242/2019 (45) affirm, in the first part, the absence of a constitutional right to suicide and the legitimacy of criminalizing assistance in and instigation to suicide, as proposed by the Milan court judges.

It is worth elaborating more closely on the several arguments made by the Constitutional Court:

- the prosecution of instigation to, and assistance in, suicide is essential to safeguard the right to life, especially of the weakest and most vulnerable people;
- in the absence of specific legislation on the subject, any professional could lawfully offer assistance in suicide (at a private residence, for profit, etc...) to patients who so wish, without

Table 1. End-of-life pieces of legislative sate of affairs in major European countries.

Country	Legislation	Specifics
Luxembourg	The law (24), enacted on March 16th, 2009	For euthanasia and assisted suicide to be legal, the following conditions must be met: • the patient is conscious and capable of understanding and wanting at the time of giving consent; • free and informed request, in writing; • the patient's clinical situation is irreversible and cause intolerable physical or psychological suffering. The doctor must obtain the consent of another professional and consult, unless the patient objects, also with the subject designated by him as a trusted person. The law also allows for the preparation of advance treatment directives, to be applied if the patient is incapacitated.
Spain	The organic law (25), passed on 18th March, 2021, lays out the regulatory underpinnings of euthanasia,	Assisted suicide is viewed as an actual right to request and obtain the help necessary to die (26).
Germany	The Federal Court of Justice, Bundesgerichtshof, on 25th June, 2010 (27), acquitted of attempted murder the lawyer of a woman who had given her consent to interrupt her life-sustaining treatments, as such an act had been carried out voluntarily and in agreement with the patient's doctors and guardians. The Assisted Suicide Bill, passed on 6th November 2015 (50), inserts a new article in the German penal code which punishes organized assisted suicide as a permanent medical offer, while leaving unpunished episodic assisted suicide by a person close to the victim.	On 26th February, 2020, the Bundesverfassungsgericht (27,28) declared unconstitutional § 217 of the German criminal code which punishes aiding and abetting of suicide for profit as contrary to the right of self-determination in death, based on the personalist principle pursuant to Art. 2 of the German Constitution: everyone is therefore free to choose to die and to be assisted by qualified and professionally competent personnel (28).
Switzerland	Swiss Penal Code (December 21st 1937) - Art. 115 of the penal code (29) punishes the instigation and assistance to suicide for selfish reasons (for example for economic gain), while the Art. 114 punishes homicide at the request of the victim, therefore euthanasia, even if practiced for honorable reasons, such as compassion for the patient's condition (30).	Assistance in suicide is legal; doctors can only supply the lethal drugs to patients, but without administering them directly: it is the patient who has to self-administer the drugs without any help other than the device designed for such a purpose (30,31).
Portugal	No current legislation. The Decree on medically assisted death was declared unconstitutional (32).	Preventive constitutionality verification was promoted by the President of the Portuguese Republic on 18th February 2021 (32), following which the decree was declared unconstitutional (judgment n. 123/2021, March 15, 2021). It was found that the notion of "irreversible condition of extreme severity according to the scientific consensus" does not limit in a sufficiently rigorous manner the situations which would justify the lack of punitive intervention by the State (30, 32-34).
France	Law against futile forms of treatment - passive euthanasia, passed on 22nd April, 2005 (35):	The law prohibits futile or unreasonable therapeutic approaches and authorizes the interruption of life-supporting treatments if these are deemed unnecessary, disproportionate or aimed only at artificially prolonging the patient's life. The law also authorizes doctors to administer palliative care to the patient, even if this has the effect of hastening death (35,36). In order to proceed with the interruption of treatments, the patient's consent is required, also through advance treatment directives, of a person indicated by him or of a family member and the favorable opinion of a board of doctors (36).

any prior check and verification as to their competence to make choices, the free and informed nature of their choice, and the irreversible nature of their health conditions;
- the reference to the European Convention on Human Rights (ECHR) (46), Articles 2 and 8, has no bearing on establishing the duty of the State to uphold the right to assistance in dying, whether from the State itself or from third parties;
- the definition of such a difficult balance is to be left to the Parliament. The Constitutional Court is in fact charged with verifying the constitutionality of already enacted legislation.

According to the Court, therefore, the rationale of the Art. 580 criminal code fulfills the purpose of protecting people who are intolerably suffering and of preserving those who decide to commit suicide from any form of interference (42). As proposed by the Milan Court, the Constitutional Court reaches a first conclusion: "the criminalization of assisted suicide cannot be considered incompatible with the Constitution". The Constitutional Justices laid out a partial acceptance, highlighting the constitutional non-compliance of the criminal argument in the part in which it punishes the conduct facilitating the suicide of patients in the conditions of D. J. Fabo, which are precisely specified by the Court. Such conditions arise from a state of vulnerability for which the safety net of criminal law should be considered unreasonably restrictive of the patient's right to self-determination when making therapeutic choices. Especially since we are dealing with developments determined by extraordinary scientific innovations, capable of saving the lives of patients in seriously compromised conditions, such patients can find themselves living in an irreversibly debilitated, even vegetative state, often dependent on life-supporting devices and in unbearable pain, which can lead them to consider their own life undignified (47). Therefore, when probing the partial constitutional illegitimacy of that criminal profile, close attention must be paid to Art. 580 of the criminal code, which does not differentiate, hence punishes, the help given to a person: a) in an irreversible condition; b) in physical or psychological pain deemed intolerable; c) kept alive by life-supporting treatments; d) capable of making free and informed decisions (42). Such a rationale therefore has paved the way for a ruling of partial inconstitutionality of Art. 580, in the part where it was found to violate Articles 2, 13, 32, subsection 2, of the Italian Constitution (48), as well as the principle of human dignity if assisted suicide does not entail the demonstrable, previously non-existent suicidal intention, or the consolidation of an already existing suicidal intention, and if those particular conditions indicated above (irreversible condition, intolerable suffering, etc...) by the person requesting it are not met. Therefore, a declaration of partial constitutional illegitimacy was issued because, as stressed by the Court and previously noted, a ruling of total acceptance could have called into question the legitimacy of the provision outlawing consensual homicide (art. 579 criminal code). When elaborating on its exculpatory rationale for cases involving patients who are in the conditions indicated above, the Court moved from the need to respect a "standard of equality" between the effects of Law 219/2017 (49) and the request for assisted suicide, pointing out that it would be discriminatory to allow, for similar situations, a different treatment with respect to the final desired outcome of ending one's own life, as allowed by the law governing informed consent and prohibited by Art. 580 criminal code. The Court then went on to argue that "If in fact the cardinal emphasis on the value of life does not exclude the obligation to respect the decision of the patient to put an end to it by interrupting life-sustaining treatments - even when this requires active material conduct by third parties (such as the shutdown of a machine, accompanied by the administration of continuous deep sedation and pain therapy) - there is no reason why such a core value should be viewed as an absolute barrier, enforced by law, to the acceptance of the patient's request for help that would be able to save them from what they view as contrary to their own notion of dignified death" (50). Similar situations are thus treated differently, with the result that some people may end up being "sentenced to live" against their will and their own perception of dignity(51). In order to avoid a legal vacuum, the Ordinance left it up to the lawmakers to put in place the necessary legislative responses within a year. Once the deadline expired with no positive outcome, the Court recognized the legislators' failure and issued ruling

n. 242/2019 (52) in order to remove the constitutional vulnerability, already found by Ordinance no. 207/2018, by deriving the constitutionally necessary criteria from the complexities of the current system. Such a second step aimed at legitimizing the defining conditions of assisted suicide mainly refers to Law 219/2017 and its "medicalized procedure". Therefore, the verification of the conditions that make assisted suicide legitimate should be carried out by public healthcare facilities, in order "to avoid abuses which could harm vulnerable patients, to guarantee their dignity and to spare them unnecessary suffering" (52). The Court also required that medical facilities rely on the preliminary opinion of local ethics committee. As for Art. 12, subsection 10, letter 'c' of Legislative Decree no. 158/2012, in the Art. 1 of the Decree of the Minister of Health 02/08/2013 and Articles 1 and 4 of the Decree of the Minister of Health 09/07/2017, the Court considered ethics committees capable of implementing and enforcing safeguards in the interest of vulnerable patients (53). As for the patient's free and informed will to resort to assisted suicide, the Court referred to Article 1, subsection 5, of Law 219/2017, which codified the right to refuse or the interruption of treatments, even life-saving ones, or ongoing support "for the person capable of acting" and whose manifestation of will must be acquired "in the ways and with the tools most suited to the patient's condition" and documented in writing or through video recordings or, for the disabled, through devices enabling them to communicate, "without compromising the possibility that the patient may change their mind, which moreover, in the case of assisted suicide, entails that they retain control over the final act that triggers the lethal process at all times". Ultimately, the Court deemed not punishable those who facilitate the execution of the suicidal intent, autonomously and freely formed, of a patient artificially kept alive, with an irreversible condition causing physical and psychological suffering which they deem intolerable, but fully capable of making free and informed decisions. While waiting for the necessary legislative interventions by the national Parliament, the Court has linked non-punishability to compliance with the procedures established by the legislation on informed consent, palliative care, continuous deep sedation (Art. 1 and 2 of Law 219/2019) and upon verification of both the required conditions and the methods of execution by a public healthcare facility, after hearing the opinion of the local ethics committee. Both the Constitutional Court Ordinance and ruling show a lack of any clear and unequivocal definition of "assisted suicide" (Article 580 of the Criminal Code), with the risk of involving situations which may be more akin to consensual homicide (art. 579 criminal code) (54). The terminology used by the Court in the Judgment (55) is that of "administration of drugs capable of causing the patient's death within a short period of time" and in the Ordinance (54), the possibility for "certain patients to end their suffering through the administration of a drug capable of rapidly causing death", without making any distinction between those who die at their own hands and those who rely on a third party. Hence, among the requisite criteria to make the procedure legitimate, there is no absolute need for the lethal chemicals to be self-administered by the patient (as it is the case in Switzerland). Furthermore, the Court's ruling, by requesting the prior opinion of the local ethics committee, raised quite a few questions. The activity currently carried out by such bodies, in fact, concerns the approval of studies for "drug experimentation". Ethics committees will have to play an active role of control, i.e. express an opinion on specific clinical cases, verify that the patient's wishes and conditions have been respected, and support the patient in weighing their decision.

The law that may be on the horizon: the draft bill "provisions on voluntary medically assisted death", 10th March 2022

The Constitutional Court, as highlighted above, has stressed the need for a legislative intervention. To that end, the Italian Parliament Chamber of Deputies gave the go-ahead for the text on the "directives on medically assisted voluntary death" on 10th March 2022, with 253 votes in favour, 117 against and one abstention (55).

For the sake of thoroughness, it is worth briefly examining the articles constituting such legislation.

Table 2 briefly elaborates on each relevant articles and core provisions therein.

Table 2. Break-down of the bill "directives on medically assisted voluntary death", passed by the Italian Parliament on 10th March 2022.

Article	Highlights of core provisions
1	Article 1 outlines the framework in which assisted suicide is legitimate: "This law governs the prerogative on individuals affected by incurable diseases with a poor prognosis or an irreversible clinical condition to request medical assistance, in order to autonomously and voluntarily put an end to their lives, within the limits and under the conditions established by this law and in compliance with the principles of the Italian Constitution, the European Convention on Human Rights and the Charter of Fundamental Rights of the European Union".
2	Article 2 elaborates on the fundamental features of medical assistance in dying: "By medically assisted voluntary death we mean the death caused by an autonomous act by which, following the process governed by the provisions of this law, one's life ends in voluntary, dignified and aware way, with the support and under the control of the National Health Service". Such an "act must be the result of an actual, free and conscious will of a subject fully capable of understanding and wanting".
3	Article 3 governs assumptions and conditions: "The person who, at the time of the request, has reached legal age, is capable of understanding and willing and of making free, current and aware decisions, can apply for voluntary medically assisted death, adequately informed, and who has previously been involved in a path of palliative care in order to alleviate her state of suffering and has explicitly refused them or has voluntarily interrupted them. This person must also be affected by a pathology certified by the attending physician or specialist doctor".
4	Article 4 establishes that two certificates, from the general practitioner and the specialist, will not be necessary to ascertain the presence of the requirements for access to assisted suicide, but only one will suffice. The law also regulates the bureaucratic details of the request, which must be made in writing (or video, in the presence of two witnesses, if it is not possible to write) and must be authenticated. It can be revoked at any time.
5	Article 5 regulates the modalities of medically assisted voluntary death.
6	Article 6 regulates conscientious objection. The provision acknowledges the right of doctors and health personnel to conscientious refusal, as it also happens with abortion (56) and other morally and ethically controversial procedures and services (57-59), but specifies that "the authorized public hospital bodies are required in any case to ensure access to the procedures provided for by this law. Regional authorities are charged with overseeing and guaranteeing its implementation".
7	Article 7 concerns the establishment of committees for clinical evaluation, committees which must be present in the various local health authorities.
8	Article 8 guarantees immunity for doctors, excluding their punishment in case of assisting suicide. The retroactive law also provides for a sort of amnesty for those who have been convicted of having helped and supported the person to resort to medically assisted death.
9	Article 9 concerns the final provisions which, after the definitive go-ahead, will allow for the law to get into force.

It is rather hard to imagine what route this bill will eventually take, but it will certainly be a winding and uncertain one. It is relatively common for Parliament to ignore or leave unanswered for far too long the indications of the Constitutional Court, which dutifully points to the need to bring legislation in line with Constitutional precepts.

Conclusions

Our hope is that when dealing with highly contentious end of life issues, the legislator will make a commitment not to leave the right to die in the vagueness of the various judicial interpretations; such a right is in fact recognized by constitutional norms or by principles of equality and reasonableness, as reaffirmed by several legislative principles in our legal system. The Parliament should therefore strive to find a reasonable agreement between the parties, in line with the rules and indications received from the Court and able to ensure protection of human dignity, even in the dramatic phase of the end of life, avoiding a "transfer of tasks from the legislator to the judges", with the consequence of passing on to the people ideologically skewed rulings which, certainly, do not serve the core principle of the "certainty of the law". On a strictly ethical, and therefore deontological,

level, doctors will in any case find themselves, as for other situations (e.g. abortion), first having to decide on the moral legitimacy of their work towards those who have already expressed this choice while fully aware, and who are still able to demonstrate such a conviction. Therefore, the effective contribution to the interruption of life will have to be subject not only to the decision of the individual doctor, but also, as unfortunately often happens, to the aid of an entire department, where the patient's survival had hitherto been guaranteed by a team. It follows that in hospital structures, in addition to the so-called hospice wards, where the terminally ill take refuge, there are also similar structures capable of leading the patient to death, with highly motivated and specialized personnel, for whom, training, reflection and rest times must be guaranteed in order to prevent occupational burnout, given the unavoidable emotional involvement. From an operational point of view, such issues will have to be discussed within the specialization schools, in order to perceive both the possible motivations underlying such a career choice, albeit occasional, and the needs of society for the formation of such permanent bodies. Given the relative rarity of euthanasia use relative to the population, these doctors and paramedics will be able to continue to operate within the wards where they belong, to be called upon if necessary, as a sort of "reservists". Furthermore, a sort of anonymity should also be guaranteed to these operators, so that they cannot be singled out as "immoral" by those who do not share their choices. Above all, patients for whom the prospect of death is desirable should not be forced to travel abroad, nor should they be burdened by the idea of potentially exposing anyone who directly or indirectly assists them in dying to the risk of a potentially life-changing criminal proceeding.

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References

1. Mercadante S, Masedu F, Degan G, Marinangeli F, Aielli F; "Home Care Italy" group (HOCAI group). Physicians' Attitudes Toward Euthanasia and Assisted Suicide in Italy. J Pain Symptom Manage. 2018 Dec;56(6):e1-e3. doi: 10.1016/j.jpainsymman.2018.09.007.
2. The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. Signed on 4th April 1997. Came into force on 1st December 1999. Available online: https://rm.coe.int/168007cf98 (Accessed on 3rd January 2023).
3. Universal Declaration of Human Rights. Proclaimed by the United Nations General Assembly in Paris on 10th December 1948. Available online: https://www.un.org/en/about-us/universal-declaration-of-human-rights (Accessed on 3rd January 2023).
4. Dolci M, Favero C, Toumi W, Favi E, Tarantini L, Signorini L, Basile G, Bollati V, D'Alessandro S, Bagnoli P, Ferrante P, Delbue S. Human Endogenous Retroviruses Long Terminal Repeat Methylation, Transcription, and Protein Expression in Human Colon Cancer. Front Oncol. 2020 Oct 27;10:569015. doi: 10.3389/fonc.2020.569015.
5. Monaco AP. Joseph Edward Murray, M.D., 1919-2012: pioneering transplant and reconstructive plastic surgeon and scientist, nobel Laureate, humanitarian-an appreciation. Transplantation. 2013 Apr 15;95(7):903-907. doi: 10.1097/TP.0b013e3182895cf2.
6. Signorini L, Dolci M, Favi E, et al. Viral Genomic Characterization and Replication Pattern of Human Polyomaviruses in Kidney Transplant Recipients. Viruses. 2020 Nov 9;12(11):1280. doi: 10.3390/v12111280.
7. Montanari Vergallo G, Busardò FP, Zaami S, Marinelli E. The static evolution of the new Italian code of medical ethics. Eur Rev Med Pharmacol Sci. 2016;20(3):575-880.
8. Petrini C. After the Italian Constitutional Court's ruling on the absence of criminal liability for assisted suicide: the role of ethics committees and clinical ethics. Editorial. Ann Ist Super Sanita. 2019 Oct-Dec;55(4):311-313. doi: 10.4415/ANN_19_04_01.
9. Marinelli E, Busardò FP. Assisted suicide: article 17 of the Italian Code of Medical Ethics follows in the footsteps of the Italian Constitutional Court's landmark ruling. Eur Rev Med Pharmacol Sci. 2020 Oct;24(20):10309-10312. doi: 10.26355/eurrev_202010_23376.
10. Montanari Vergallo G, Zaami S, Bruti V, Signore F, Marinelli E. How the Legislation on Medically Assisted Procreation Has Evolved in Italy. Med Law. 2017; 36(2): 5-28.

11. Rallo G, Negro F, Consalvo F, Piersanti V, Marinelli S. Medically assisted procreation in times of COVID-19: what impact on health care system organization and the reproductive rights of couples? Acta Biomed. 2021 Nov 3;92(5):e2021275. doi: 10.23750/abm.v92i5.11900.
12. Cippitani R. Ethical issues and law-making power: how European case law has rewritten Italian law on medically assisted reproduction. Monash Bioeth Rev. 2019 Oct;37(1-2): 46-67. doi: 10.1007/s40592-018-0088-8.
13. Malvasi A, Zaami S, Tinelli A, Trojano G, Montanari Vergallo G, Marinelli E. Kristeller maneuvers or fundal pressure and maternal/neonatal morbidity: obstetric and judicial literature review. J Matern Fetal Neonatal Med. 2019 Aug;32(15):2598-2607. doi: 10.1080 /14767058.2018.1441278.
14. Marinelli S, Cucinella G, Basile G. COVID-19 and female fertility: the flaws of Italian Law 40/2004 on assisted procreation in pandemic times. Acta Biomed. 2022 Oct 26;93(5):e2022316. doi: 10.23750/abm.v93i5.13765.
15. Gruppo di Lavoro in Materia di Aiuto Medico al Morire. Aiuto medico a morire e diritto: per la costruzione di un dibattito pubblico plurale e consapevole [Medical assistence to die, and law.]. Recenti Prog Med. 2019 Oct;110(10):462-472. Italian. doi: 10.1701/3246.32161.
16. Veronesi U. Il diritto di morire: la libertà del laico di fronte alla sofferenza. Mondadori, 2005, p.25.
17. Veshi D, Koka E, Venditti C. A New Law of Advance Directives in Italy: A Critical Legal Analysis. J Law Med. 2019 Apr;26(3):702-710.
18. van der Arend AJ. An ethical perspective on euthanasia and assisted suicide in The Netherlands from a nursing point of view. Nurs Ethics. 1998 Jul;5(4):307-318. doi: 10.1177/096973309800500404.
19. Mangino DR, Nicolini ME, De Vries RG, Kim SYH. Euthanasia and Assisted Suicide of Persons With Dementia in the Netherlands. Am J Geriatr Psychiatry. 2020 Apr;28(4):466-477. doi: 10.1016/j.jagp.2019.08.015.
20. Montanari Vergallo G, Busardò FP, Berretta P, Marinelli E, Zaami S. Advance healthcare directives: moving towards a universally recognized right. Eur Rev Med Pharmacol Sci. 2018 May;22(10):2915-2916. doi: 10.26355 /eurrev_201805_15043.
21. Van Nieuwenhove M, Ricou B. Euthanasie et suicide assisté - Vision comparative et réflexive entre la Belgique et la Suisse [Euthanasia and assisted suicide - Comparative and reflexive vision between Belgium and Switzerland]. Rev Med Suisse. 2021 Apr 7;17(733):708-711. French.
22. Nanner H. The effect of assisted dying on suicidality: a synthetic control analysis of population suicide rates in Belgium. J Public Health Policy. 2021 Mar;42(1):86-97. doi: 10.1057/s41271-020-00249-8.
23. McEvoy P. Euthanasia, ethics, and the Gordian Knot: is the Hippocratic Code obsolete? Br J Gen Pract. 2015 Dec;65(641):624-5. doi: 10.3399/bjgp15X687721.
24. Euthanasia in Belgium, the Netherlands and Luxembourg. Prescrire Int. 2013 Nov;22(143):274-278.
25. Velasco Bernal C, Trejo-Gabriel-Galan JM. Leyes de eutanasia en España y en el mundo: aspectos médicos [Euthanasia laws in Spain and in the world: Medical aspects]. Aten Primaria. 2022 Jan;54(1):102170. Spanish. doi: 10.1016/j .aprim.2021.102170.
26. Bernal-Carcelén I. Euthanasia: trends and opinions in Spain. Rev Esp Sanid Penit. 2020 Sep-Dec;22(3):112-115. doi: 10.18176/resp.00020.
27. Hyde R. Germany overturns ban on assisted suicide. Lancet. 2020 Mar 7;395(10226):774. doi: 10.1016 /S0140-6736(20)30533-X. Erratum in: Lancet. 2020 Mar 28;395(10229):1038.
28. Mroz S, Dierickx S, Deliens L, Cohen J, Chambaere K. Assisted dying around the world: a status quaestionis. Ann Palliat Med. 2021 Mar;10(3):3540-3553. doi: 10.21037/apm-20-637.
29. Burkhardt S, La Harpe R. Debates about assisted suicide in Switzerland. Am J Forensic Med Pathol. 2012 Dec;33(4):410-413. doi: 10.1097/PAF.0b013e318273b83f.
30. Sprung CL, Somerville MA, Radbruch L, et al. Physician-Assisted Suicide and Euthanasia: Emerging Issues From a Global Perspective. J Palliat Care 2018; 33: 197-203.
31. Vyssoki B, Stich M, Eder-Pissarek E, et al. Angekündigter assistierter Suizid in der Schweiz – Ein Fallbericht [Announced assisted suicide in Switzerland: a case report]. Neuropsychiatr. 2021 Dec;35(4):187-191. German. doi: 10.1007 /s40211-021-00398-6.
32. Emanuel EJ, Onwuteaka-Philipsen BD, Urwin JW, Cohen J. Attitudes and Practices of Euthanasia and Physician-Assisted Suicide in the United States, Canada, and Europe. JAMA. 2016 Jul 5;316(1):79-90. doi: 10.1001/jama.2016.8499. Erratum in: JAMA. 2016 Sep 27;316(12):1319.
33. Barranha R. Existe um Papel para a Psiquiatria no Processo de Morte Assistida em Portugal? [Is There a Role for Psychiatry in Physician-Assisted Death in Portugal?]. Acta Med Port. 2020 Sep 1;33(9):629. Portuguese. doi: 10.20344/amp.14443.
34. Julião M. Letter to the Editor Regarding Barranha´s Paper: "Is There a Role for Psychiatry in Physician-Assisted Death in Portugal?". Acta Med Port. 2020 Nov 2;33(11):779. doi: 10.20344/amp.14853.
35. Aubry R. End-of-life, euthanasia, and assisted suicide: An update on the situation in France. Rev Neurol (Paris). 2016 Dec;172(12):719-724. doi: 10.1016/j.neurol.2016.09.007.
36. Boulanger A, Chabal T, Fichaux M, et al. Opinions about the new law on end-of-life issues in a sample of french patients receiving palliative care. BMC Palliat Care. 2017 Jan 21;16(1):7. doi: 10.1186/s12904-016-0174-8.
37. Italian Civil Code. Article 5. Atti di disposizione del proprio corpo. Codified by Law n. 235, enacted on 3rd April 1957. Available online: https://www.codice-civile-online.it /codice-civile/articolo-5-del-codice-civile (Accessed on 3rd January 2023).
38. Italian Criminal Code. Title XII – Dei delitti contro la persona, articles 575-623. Available online: https://www .ilcodicepenale.it/#Titolo_XII_-_Dei_delitti_contro_la _persona_artt_575-623 (Accessed on 3rd January 2023).

39. Law no. 219/2017. Norme in materia di consenso informato e di disposizioni anticipate di trattamento. Enacted on 22nd December 2017. Available online: https://www.gazzettaufficiale.it/eli/id/2018/1/16/18G00006/sg (Accessed on 3rd January 2023).
40. Cioffi A, Zaami S. Italian Law no. 219/2017: consequences on the informed consent of the psychiatric patient and on the therapeutic privilege. Riv Psichiatr. 2020 Mar-Apr; 55(2):129-130. doi: 10.1708/3333.33028.
41. Montanari Vergallo G, Gulino M, Bersani G, Rinaldi R. Euthanasia and physician-assisted suicide for patients with depression: thought-provoking remarks. Riv Psichiatr. 2020 Mar-Apr;55(2):119-128. doi: 10.1708/3333.33027.
42. Italian Criminal Code. Art. 580. Available online: https://testolegge.com/codice-penale/articolo-580 (Accessed on 3rd January 2023).
43. Supreme Court of Cassation, ruling n. 31476, issued on 6th February 1998.
44. Constitutional Court Ordinance n. 207/2018. Issued on 24th October2018.Availableonline:https://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2018&numero=207 (Accessed on 3rd January 2023).
45. Constitutional Court Ruling n.242/2019. Issued on 25th September 2019. Available online: https://cortecostituzionale.it/actionSchedaPronuncia.do?anno=2019&numero=242 (Accessed on 3rd January 2023).
46. European Convention on Human Rights. Signed 4 November 1950. Came into force on 3rd September 1953. Available online: https://www.echr.coe.int/Documents/Convention_ENG.pdf (Accessed on 3rd January 2023).
47. Paterlini M. Paraplegic man is first person to be allowed to die by assisted suicide in Italy. BMJ. 2021 Nov 26;375:n2927. doi: 10.1136/bmj.n2927.
48. Constitution of the Italian Republic. Enacted on 27th December 1947. Available online: https://www.senato.it/sites/default/files/media-documents/COST_INGLESE.pdf (Accessed on 3rd January 2023).
49. Petrini C. Will medically-assisted suicide mean the rebirth of (clinical) ethics committees in Italy? Med Leg J. 2020 Nov;88(1_suppl):26-30. doi: 10.1177/0025817220923650.
50. Delbon P, Maghin F, Conti A. Medically assisted suicide in Italy: the recent judgment of the Constitutional Court. Clin Ter. 2021 May 5;172(3):193-196. doi: 10.7417/CT.2021.2312.
51. Ricci G, Gibelli F, Sirignano A. Editorial - From ruling No. 242/2019 of the Constitutional Court to the Italian law on medically assisted death: a complex transition. Eur Rev Med Pharmacol Sci. 2022 Jul;26(13):4546-4549. doi: 10.26355/eurrev_202207_29174.
52. Constitutional Court Ruling 242, issued on 22nd November 2019. Available online: https://sentenze.laleggepertutti.it/sentenza/corte-costituzionale-n-242-del-22-11-2019 (Accessed on 3rd January 2023).
53. Busardò FP, Bello S, Gulino M, Zaami S, Frati P. Advance health care directives and "public guardian": the Italian supreme court requests the status of current and not future inability. Biomed Res Int. 2014;2014:576391. doi: 10.1155/2014/576391.
54. d'Avack L. L'aiuto al suicidio medicalizzato sotto il controllo della Corte Costituzionale. Biodiritto. Issued in September 2019. Available online: https://www.biodiritto.org/content/download/3926/46251/version/1/file/d%27avack.pdf (Accessed on 3rd January 2023).
55. Draft Bill titled "Morte volontaria medicalmente assistita". Passed by the Italian Chamber of Deputies on 10th March 2022. Available online: https://temi.camera.it/leg18/temi/morte-medicalmente-assistita.html (Accessed on 20th January 2023).
56. Morrell KM, Chavkin W. Conscientious objection to abortion and reproductive healthcare: a review of recent literature and implications for adolescents. Curr Opin Obstet Gynecol. 2015 Oct;27(5):333-338. doi: 10.1097/GCO.0000000000000196.
57. Montanari Vergallo G, Zaami S, Di Luca NM, Marinelli E. The conscientious objection: debate on emergency contraception. Clin Ter. 2017 Mar-Apr;168(2):e113-e119. doi: 10.7417/CT.2017.1991.
58. Zampas C. Legal and ethical standards for protecting women's human rights and the practice of conscientious objection in reproductive healthcare settings. Int J Gynaecol Obstet. 2013 Dec;123 Suppl 3:S63-S65. doi: 10.1016/S0020-7292(13)60005-3.
59. Zaami S, Signore F, Baffa A, Votino R, Marinelli E, Del Rio A. Emergency contraception: unresolved clinical, ethical and legal quandaries still linger. Panminerva Med. 2021 Mar;63(1):75-85. doi: 10.23736/S0031-0808.20.03921-X.

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