

EDITORIAL

After the Italian Constitutional Court's ruling on the absence of criminal liability for assisted suicide: the role of ethics committees and clinical ethics

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“Medically-assisted suicide” continues to be a subject of analysis and debate in terms of its ethical, legal, medical and anthropological aspects.

In Italy, events are ensuring that this focus remains, and two rulings from the Constitutional Court [1, 2] and the parliamentary debate associated with examination of various bills are particularly important in this regard.

This article is not intended to add personal reflections to the already considerable volume of comment on this issue, or to enter into a detailed discussion of the possible classifications of “euthanasia” and differentiations of the concept of “medically-assisted suicide”.

As we know, the Constitutional Court handed down a judgment [1] on 25 September 2019 following on from that Court's Order No 207 of 24 October 2018 [2]. The issue of constitutionality of Article 580 of the Criminal Code, in the part about the punishment of the aid to suicide, was raised by the Court of Milan, in an Order of 14 February 2018 [3], in relation to the case of Marco Cappato, who accompanied Fabiano Antoniani (a forty-year-old who had been a tetraplegic since 2014 because of a traffic accident) to the Dignitas clinic in Forch, some ten kilometres from Zurich, to commit suicide. In its Order of 24 October 2018, the Court observed that Article 580 of the Penal Code is “functional to the protection of interests worthy of protection by the legal system”, and therefore that “the indictment of assisted suicide cannot be considered incompatible with the Constitution” [2]. To enable Parliament to enact appropriate provisions on the issue, that Order deferred until 24 September 2019 any treatment of the question of the constitutionality of Article 580 of the Criminal Code (whereby “Any person who causes the suicide of another or strengthens the resolve of another to commit suicide or facilitates the suicide of another in any manner shall be punished, if that suicide occurs, with imprisonment for a period of five to twelve years”).

Because the parliamentary debate in progress has not

resulted in any legislative intervention, on 25 September 2019 the Court has held that “under certain conditions, a person who facilitates the execution of the suicide intention, autonomously and freely formed, of a patient kept alive by life support treatments and affected by an irreversible pathology, source of physical or psychological suffering that he considers intolerable but fully capable of making free and conscious decisions” is not punishable under Article 580 of the Criminal Code [1]. “Pending an indispensable intervention of the legislator, the Court holds exclusion from criminal liability to be subject to compliance with the conditions laid down by the legislation on informed consent, palliative care and continuous deep sedation (Articles 1 and 2 of Law No 219/2017) and verification of the conditions required and of the procedures for performance of the act by a public structure within the Italian national health service, following consultation with the relevant local ethics committee” [1].

Among the many implications of this intervention by the Court, some have a considerable impact on the functions of the national health service (SSN). Indeed, on the basis of Article 1 of Law No 833 of 28 December 1978, the SSN “shall be made up of the series of functions, structures, services and activities intended to promote, maintain and restore the physical and mental health of the entire population (...)” [4]. Questions will need to be asked about the compatibility between “medically-assisted suicide”, which the Court deems to fall within the practices provided by the SSN, and the three functions (promotion, maintenance and restoration of health) that the law attributes to that Service.

A further implication for healthcare institutions concerns the involvement of local ethics committees (ECs), which, according to the Court's decision, must provide an opinion in all cases involving a request for “medically-assisted suicide”.

Law No 3 of 11 January 2018 provides for (Article 2(7)) the creation of 40 “local ethics committees” by

means of a ministerial decree to be issued within 60 days following the entry into force of that Law. On the basis of that Law (Article 2(10)), the local ECs “shall have jurisdiction and authority to assess clinical trials on medical devices and on medicinal products for human use”. However, the ministerial decree has not been issued, and 90 ECs have been created on the basis of the Decree of 8 February 2013 [6]. According to that Decree, the ethics committees’ “responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection. Where they are not attributed to specific bodies, ethics committees may also undertake consultative functions in relation to ethical issues associated with scientific and care activities, in order to protect and promote the dignity of the person”. It is clear that the current legislative framework assigns functions to ECs that are crucial for approving clinical trials. It is also clear, as has been noted by the Italian Committee for Bioethics [7], that there is a lack of an appropriate legislative framework for ECs in terms of clinical ethics and of initiatives to promote clinical ethics [8]. Indeed, Italy does not currently have national regulations or initiatives, making do only with certain regional measures (and in particular those applicable in Veneto, which created ECs for clinical aspects in 2004 [9, 10], and in Friuli Venezia Giulia [11]).

This lacuna must now be addressed: the decision by the Constitutional Court imposes a requirement for an opinion from a local EC for requests for “medically-assisted suicide”.

In the current situation, three possible scenarios have been identified in particular:

A first option is that the 40 local ECs required to be created on the basis of the Law of 11 January 2018 (Article 2(7)) [5] also deal with clinical cases (including requests for “medically-assisted suicide”).

A second possibility is that appropriate national (and subsequently regional where necessary) measures be enacted to create ECs specifically responsible for assessing clinical cases.

The third possibility falls within the new framework provided by the Law of 11 January 2018 [5], which, as we have already noted, requires a reduction in the num-

ber of committees from 90 to 40. Assuming that the 40 ECs created on the basis of the implementing decree for that Law coincide with the 40 existing committees (excluding variations in composition), 50 committees would be destined for elimination.

The existing committees not covered by the future decree creating the 40 local ECs responsible for assessing clinical trials could be authorised for assessment of studies other than clinical trials (such as observational studies, studies on biological samples, etc.).

The first option seems difficult to implement, specifically because the imminent implementation of Regulation (EU) No 536/2014 [12] means that the workload of local ethics committees responsible for assessing clinical trials is going to increase. Consequently, it will be difficult for these committees to cover clinical cases as well.

The second possibility is a desirable outcome: in Italy, the promotion of committees and services for clinical ethics has hitherto been lacking and the lacuna must be addressed. However, this process inevitably requires a lengthy period of time, while the Constitutional Court’s decision requires that these systems be operational in the short term.

The third option is seen as potentially being particularly effective, because it is immediately operational (among other reasons). This would make it possible to avoid a dispersal of the expertise accumulated by ECs, which is often of significant value. However, this could also involve work along the same lines as for the second option in order to promote ECs and services dedicated to clinical ethics at national level.

The procedures applied by ECs to rule on cases of “medically-assisted suicide” must be appropriately regulated. In any case, it is hoped that opinions from ECs will be mandatory and non-binding, a view also recommended by the Italian Committee for Bioethics [7].

Acknowledgement

At the time of publication of this article, the text of the ruling of the Constitutional Court has not yet been deposited. Therefore, the article is based on the press release issued by the Constitutional Court on 25 September 2019.

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