Author’s response to reviews

Title: A review and analysis of the new Italian law 219/2017: “Provisions for informed consent and advance directives treatment”.

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Author’s response to reviews:

Dear Editor

BMC Medical Ethics.

I’m pleased to send you the revised version of the paper by Di Paolo et al, METH – D -18-00090. We greatly appreciate your comments and reviewers’ suggestions and criticisms and reviewed the paper accordingly. Changes are outlined in the text by the track changes system.

Point by point response.

Editor Comments

We structured the abstract in accordance with BMC Medical Ethics submission guidelines, changing the subheadings into: Background, Main text and Conclusions.

Regarding the overlapping sections:

we removed section beginning with ‘On this point’ and ending with’ … and consider …’.
we edit section beginning with ‘shared care planning’ and ending with ‘… with complex medical and social needs’.

we partially rewritten the paragraph on conscientious objection, thus removing the section beginning with ‘the crucial questions that aims” and ending with ‘ … CO should result in harassment …’ and editing the section beginning with ‘This would potentially …’ and ending with ‘hiring of additional personnel’.

Reviewer 1.

According to reviewer’s suggestions, a native English speaker checked the paper for grammar.

In particular:

we changed the expressions ‘evaluation perspectives’ and ‘consensual relationality’ in the abstract.

Pag. 6: we changed ‘shared planning care’ into ‘shared care planning’

Pag. 10 we changed ‘talk can be therapeutic’ into ‘conversation’

Pag. 10 we modified the sentence containg the term “hospitalist communication”.

Pag.13 we changed the sentence ‘shared participation in medical treatment’ in ‘shared decision making’.

Pag.14 we modified the sentence ‘integrated reading’.

Pag. 15 we replace the phrase ‘future self’ by and everyday sentence.

Pag. 16 we changed ‘draw up ADs’ into ‘draft/write ADs’.

Pag. 24 we changed the sentence ‘have helped to produce a law’ into ‘have paved the way for a law’.

We divided the section ‘Specific points’ into different subheadings: Informed consent, Communication time, Shared care planning, Advance treatment directives, Conscientious objection.

Regarding points 3 and 4 we further specified in the text that the new Italian law does not explicitly mention the possibility of conscientious objection for healthcare professionals caring for patients who have expressed their will regarding medical treatments. Indeed, the law states (art. 5, paragraph 5) that “the physician is required to respect the ADds”, meaning that it is thus letting it means a legally binding and not simply advisory value for them, not an advisory one.
Only when ADs appear to be clinically inappropriate is the physician legitimated to disregard them. In fact, in the same article 4 it is established that ‘ [...] the doctor takes into account the ADs, which may be disregarded, in whole or in part, by the same doctor, in agreement with the trustee, if they clearly appear incongruous or do not correspond to the current clinical condition of the patient or if there are therapies which were unforeseen at the time of writing which would offer sound possibilities for improved living conditions. [...]’. Furthermore, as above mentioned above, the law evokes the general principle that ‘the patient cannot demand health treatment contrary to the law, professional ethics or good clinical-care practice; with regard to such requests, the doctor has no professional obligations’.

Other points:

Pag. 2 we changed ‘strong relationship’ into ‘optimal relationship’.

Pag. 2 we changed ‘preferences of a currently disabled person’ into ‘person unable to express their will’.

Pag. 5 we replaced the terms ‘cultural clash’ into ‘cultural debate’.

Pag. 5 we agree with the reviewer regarding her doubts on the term ‘perfect moment’. Since the law does not mention this term we delete ‘perfect’ (probably a perfect moment does not exist) and use the term ‘adequate’ that better expresses the value of the time to make a choice in healthcare planning.

Pag. 9. We added some sentences (and references) trying to providing background for the current climate of defensive medicine existing in Italy.

Pag. 12. We agree with the reviewer and delete ‘with dignity’ since it was not a neutral term.

We deleted ‘in our opinion’ from the text.

Reviewer 2

We changed the title according to reviewer’s suggestion.

We changed the sentence ‘it is the point of arrival in a process …’ into ‘it is the culmination of a year-long process …’.

Regarding the use of the sentence ‘highly sensitive and divisive’, we used the two aggettivi aiming at expressing the fact that the themes addressed in the law have, over the years, stimulated a cultural and ethical debate also at a national level in Italy (see references 2-10). Over the years, numerous bills have been proposed without ever becoming law. Finally, in December 2017 the
law was approved by the Italian Parliament. In effetti, highly – public cases (Englaro, Welby, etc) have raised visibility of the issues. However, following the reviewer’s suggestions, we changed the terms ‘highly sensitive and divisive’ into more neutral term ‘contentious’.

We changed ‘termination of treatment’ into ‘withdrawal of treatment’.

We amended the misprint ‘aw’ into ‘law’.

In abstract conclusion we modified the sentence ‘… and that will call health-care institutions’.

We shortened the abstract, deleting some sentences.

At the end of the abstract we added some sentences, explaining the purposes of the paper as suggested by the reviewer.

We agree with the reviewer regarding his doubts on the term ‘perfect moment’. Since the law does not mention this term we delete ‘perfect’ (probably a perfect moment does not exist) and use the term ‘adequate’ that better expresses the value of the time to make a choice in healthcare planning. We modified this part and delete references accordingly.

We agree that the law acknowledges ‘the autonomous patients’ right to make his or her own healthcare-related decisions’ and modified the text accordingly.

We agree that is really the ‘principle of respect for patient autonomy’ not ‘principle of autonomy’ and modified the text accordingly.

We changed ‘care relationship’ into ‘doctor-patient relationship’.

At the beginning of the section specific point, we modified the sentence according with the reviewer’s suggestion, changing ‘informed consent’ into ‘principle of respect for patient autonomy’ and the term ‘competence’ with ‘decisional capacity’.

We added in the text the fact that clinicians are shielded from malpractice suits and penal liability as well.

We perfectly agree with the reviewer’s words and added a sentence at the end of the paragraph ‘shared care planning’.

We added a sentence focusing on the fact that ADs can be viewed as an extension of the fully autonomous person.

We specified in the text that the law does not stipulate what can and cannot be put into an AD. It only refers to the introductory article that affirms the general principle that a patient cannot demand treatments contrary to the law, the professional ethics, or to the good clinical practices. In the face of such eventual requests the physicians have no professional obligations. Formal
requirements are necessary to stipulate ADs, as they must be drawn up as public act or private act authenticated by a notary.

We specified that the patient can get information from many sources.

Finally, following the reviewers’ suggestions we partially rewritten the paragraph regarding CO, focusing on the fact that the law does not provide for CO.

The operational practice of the law is still in progress in Italy, so we still do not know how important the issue of CO will be and how it will be attempted to resolve it.

Best regards,

Emanuela Turillazzi, M.D., pHd

Pisa, 21 September 2018