Reviewer's report

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

Version: 0 Date: 24 Jul 2018

Reviewer: Ruth Horn

Reviewer's report:

This paper reports on the Italian law on advance directives (ADs) which came into force in 2017. To my knowledge, few has been published on this topic in English and the paper gives an overview of the law's content. I think it would be an interesting contribution in the BMC Medical Ethics; yet before publication, I would like to invite the authors to address some substantial issues:

1. Generally, the paper is clearly written, yet it would be good to check it for grammar, wording and clarify some of the expressions used, e.g.:

   Abstract 'evaluation perspectives' find better expression
   page 2 'consensual relationality' (explain what you mean by this);
   page 6 'shared planning care' should be shared care planning;
   page 6 'end stage of a patient's biological life' find better expression
   page 9 'Talk can be therapeutic' - this should be 'conversation...';
   page 9 clarify meaning of 'hospitalist communication' (explain what you mean by this); page 11 'shared participation in medical treatment' should be 'shared decision making'; page 12 'integrated reading' (clarify);
   page 13 'future self' - please refer to the philosophical concept and expand on its meaning or replace by an everyday word
   page 14 - 'to draw up ADs' should be 'draft/write ADs';
   page 17 'have helped to produce a law' find better expression .... etc.

2. The section 'Specific points' needs to be divided into different sub-headings/-sections!

3. From page 13, the authors discuss the law's articles on ADs '[a patient] can, through the ADS, express his/her own will regarding health treatments as well as consent or refuse with regard to [...]'. Besides checking the English translation of this paragraph, I am missing
discussion about the actual meaning of this article. As it is translated here, the law 'allows' patients to write an AD. This does not mean yet that an AD is legally binding. Being allowed to write and express a wish does not imply that the health professionals have to respect this wish. At its best, it suggests that ADs will have advisory value for physicians. When French law first mentioned ADs in 2015, it stated that patients 'can' write an AD but did request physicians to respect the AD. Only in 2017, the French law clarified that ADs are legally binding. As far as the authors present the Italian law, it seems that it recognises only advisory value of ADs but health professionals are not legally bound to respect them. Hence, a more critical and analytical discussion of the Italian public debate around contentious objection (from page 15) would be helpful as this debate mirrors confusion among the population or intentional misrepresentation of the law's content among campaigners. A more intensive discussion of the legal meaning of the law would be helpful here.

4. Furthermore, the public debate around contentious objection in Italy seems to conflate the right to CO - this would be the case if ADs would be legally binding for doctors - and the validation of ADs. In case a physician hesitates to implement an AD that is 'clearly incongruous or does not respond to the current clinical condition of the patient…' (page 17), this is not a case of CO but of an invalid AD not representing the patient's wish in the given situation. The authors should discuss this conflation critically rather than taking it as granted and lead their discussion based on this misunderstanding.

Besides the more substantial issues, I would like to make some minor comments the authors should address before publication:

1. Page 2 line 23 'concepts that should be part of a strong relationship' - based on what arguments/grounds? Define 'strong' relationship

2. Page 2 line 60-page 3 line 1 'preferences of a currently disabled person' - this should be sth like 'person unable to express their will…' but not 'disabled person'!

3. Page 5 'cultural clash' - I am not sure this is a matter of a 'cultural clash'

4. Page 5 line 46 'the right to a perfect moment' - problematize/discuss 'perfect' moment rather than using it in an uncritical way; or put it in '…' if this is direct translation from Italian law

5. Page 8 line 23 'current climate of defensive medicine' - explain, provide background for this 'current climate'

6. Page 11 line 14 'together and with dignity' - is this the authors' interpretation of dignity? Problematize/define concepts like dignity rather than presuming their meaning or replace by value neutral terms
7. Page 14 line 60 'in our opinion' an academic paper should not be based on own opinions but on arguments or evidence!

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Unable to assess

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Yes

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

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Please indicate the quality of language in the manuscript:

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