**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:** 05 Aug 2018

**Reviewer:** Paul Mueller

**Reviewer's report:**

Comments to authors:

This is a thoughtful and helpful review of the new Italian Law 219/2017 'Provision for informed consent and advance treatment directives'.

* Title: The use of the term "Kairos" is interesting, but is used once elsewhere, and not effectively. I think the title should be re-written to describe what the article actually is: A review and analysis of the new Italian Law 219/2017 'Provision for informed consent and advance treatment directives'.

* Abstract: Rather than saying "It is the point of arrival in a process…", it might be better to say "It is the culmination of a year-long process…"

* Abstract: Why are these issues "highly sensitive and divisive"? Is this a generally accepted impression? Is it based on polling or survey data? If so divisive, why was the law passed? Were there grass-roots efforts to pass the law? Did highly-public cases in Italy raise visibility of the issues (as in the US)?

* Abstract: I like the term "withdrawal of treatment" rather than "termination of treatment".

* Abstract: "The aw" should be "The law".

* Abstract: A term often used is "shared decision-making" in addition to "shared planning".

* Abstract: Advance treatment directives (advance directives, living will, etc.) are written documents that document patients' goals, values and wishes for future healthcare decisions in the event they lose decision-making capacity and completing ADs is part of a greater process of advance care planning.

* Abstract Conclusion: The last clause "…and that will call health-care institutions…” is unclear to me.
Background: Too long.

Background: As above, please provide data and references as too why these issues "are highly sensitive and divisive" in Italy.

Background: At the end of this section, describe the purpose/objective of the article (e.g., "In this article, we describe and analyze the new Italian Law 219/2017 'Provision for informed consent and advance treatment directives' and provide...").

Background: "...may be viewed ad..." should be "...may be viewed as..."

The new law: time to decide: On the use of the term, "Kairos" and the phrase "...the right to a perfect moment...to make a decision." I doubt such a moment exists for most people. I believe the literature suggests that just about any time is appropriate to discuss healthcare-related values, goals and preferences with patients and that these discussions should especially occur when there has been a change in a patent's clinical status. These are not single discussions. Rather, ongoing review and discussions with relevant documentation (i.e., advance care planning).

The new law: time to decide: The law allows does not acknowledge "...the patient's right to exercise his or her decisional capacity", but rather acknowledges "the autonomous patient's (i.e., a patient with decisional capacity) right to make his or her own healthcare-related decisions."

The new law: time to decide: It's really the "principle of respect for patient autonomy", not "principle of autonomy." The difference is important and relevant to the article.

Specific points: In the first line, say "doctor-patient relationship" instead of "care relationship", so the reader knows exactly to what you are referring.

Specific points: The authors state "This is based on informed consent in which..." Would again weave in the term "principle of respect for patient autonomy". As an aside, in most jurisdictions, "competence" is a legal term and determined by courts of law. "Decisional capacity" is a clinical term and is the preferred term.

Specific points: Regarding fear of litigation and being shielded from malpractice, does the new law also protect doctors from criminal charges such as manslaughter and murder?

Specific points: Regarding "shared care planning", I would emphasize that it not only promotes patient-centeredness, etc. it emphasizes respect for patient autonomy—respecting patients' healthcare values, goals and preferences and incorporating them into care plans. This is what we would all want for our own care. This is the gist of the new Italian law.

Specific points: What if a patient or their surrogate/agent/trustee demands non-beneficial or unreasonable treatments? Does the law and its CO provision address this scenario?
Specific points: An AD ought to be viewed as an extension of the fully autonomous person.

Specific points: Does the law stipulate what can and cannot be put into an AD? Witnesses or notary? Other requirements?

Specific points: Patients get information from many sources, not just the Internet. This fact highlights that doctors should be involved in the advance care planning process and review patients' values, goals and preferences.

Specific points: "In this debate it is noteworthy that compliance with ADs generally implies a 'non-act'…" I agree. If a doctor expresses CO, the authors argue, they would do a positive act such as intubation. I see their point, but the argument is weak and a rhetorical question is asked. I think this paragraph should be developed further. For example, what if the patient has a reversible process such as pneumonia for which the doctor strongly believes only a day or two of intubation and mechanical ventilation is needed, but the patient or surrogate steadfastly refuses intubation? Could the authors describe their approach to such a situation in light of the new law? (In the US, the patient's wish would be respected.) What happens if the doctor is steadfast in his/her CO?

Specific points: Correct spelling: "...held undesirable…"

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

No

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Unable to assess

Are the conclusions drawn adequately supported by the data shown?
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Yes

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