Reviewer’s report

Title: Legal medicine implications in fibrinolytic therapy of acute ischemic stroke

Version: 1 Date: 16 May 2019

Reviewer: N. V. Todd

Reviewer's report:

I liked this paper in principle but it has a number of problems. I emphasise that I will comment upon the law as I see it from a UK perspective. I have no knowledge of Romanian law, if that is different. The subject of the paper is relevant and interesting. However the analysis of the legal principles it is flawed.

In many places they say that informed consent is mandatory; this is incorrect. It is correct for elective procedures but not in an emergency. In traumatic head injury (as one of many examples of emergency treatment) the patient will commonly be unconscious and unable to give consent. Neurosurgeons can treat on the legal basis of the best interests of the patient. If there is a complication of surgery the doctor's defence is necessity (to understand this imagine pulling a man out of the pathway of an oncoming car during which you dislocate his shoulder; it was necessary to pull him away to save his life, the complication is unfortunate but not negligent). Many of the principles of best interest judgments in neurosurgery (and many other disciplines) apply to thrombolysis for stroke.

I will deal with the cases putting in my analysis of the law:

Case 1. The patient had a stroke but the timing of stroke was not known. This, in all of the guidelines, prohibits fibrinolysis. The family complained. Doctors cannot be pushed to treat patients beyond the limits of the scientific knowledge. The decision not to treat was medically and legally correct.

Case 2. Very similar to case 1. The CT demonstrated a stroke that contraindicated treatment. Doctors cannot treat outside accepted guidelines (if they exist).

Cases 3 and 4. The patient could not give informed consent, the family refused consent. The doctor's duty of care is to the patient not the family. Applying the best-interest test treatment should have been given. It is obviously desirable to keep the family informed and to be sympathetic to their views but they cannot prevent necessary treatment. In neurosurgery we faced this decades ago when it was thought that we needed to obtain the relatives consent to switching off a ventilator in a brain dead patient. We do not need their consent, ventilation has no benefit to such a patient and can be discontinued.

Case 5. Perfect management.
Cases 6 and 7. Patients who are legally competent have the right to refuse any and all treatments even if their decision is illogical and/or a threat to their life. The patient can, of course, change their mind.

I liked the paragraph at lines 322-329.

The idea of a paper that addresses informed consent in treating stroke patients within the very tight timeline for fibrinolysis is interesting and potentially useful. I note that none of the authors is a legal or bioethical expert and, I am afraid this shows. I recommend that the authors take on someone who has such expertise to reframe the legal issues appropriately. This would lead to some interesting conclusions. Cases 1, 2, 5, 6 and 7 were managed correctly. Cases 3 and 4 were not.

There needs to be correction of the text from an active English language speaker.

I hope the authors are happy to revise this because I think it would be a good paper.

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?
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Not relevant to this manuscript

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