Reviewers report

Title: Consenting the Vulnerable: The Informed Consent in Advanced Cancer Patients in Mexico

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Reviewer: Neema Sofaer

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Verastegui presents the results of a survey designed to assess the quality of informed consent in five pharmaceutical-sponsored international clinical trials in Mexico City. The author argues that the quality of informed consent is inadequate and that therefore the process of informed consent does not -- contrary to what has been argued -- guard against the commission of moral wrongs in clinical trials conducted in the developing world. Several studies have already shown that subjects in the developing world cannot understand informed consent forms as they are written. This paper adds valuable data from a new research context to support this consensus.

Major Compulsory Revisions

There are, however, two major flaws to argument. First, the author infers that the quality of informed consent is low from data that indicates that the informed consent form is not written in a form that the subject can understand. This inference fails: the quality of informed consent can be high even if the subject does not understand the consent form when she reads it if someone explains its contents to her in terms that she can understand. Second, the author draws ethical conclusions from the alleged fact that the quality of informed consent is low. It is unclear what these conclusions are and how her data supports them. If the author wishes to draw ethical conclusions, she should take more time to explain and support them. My other objections concern particular passages or claims. I have listed them below under the titles of the sections in which they occur.

Results (p. 2)
It is unclear who considered the consent “lengthy and complex to understand”.
It is unclear what is meant by the claim that “only the doctor was considered to consent”.

Conclusion (p. 3)
It is unclear what is meant by “ethical panacea”. One possible interpretation is “effective means to avoid exploitation”, but the author does not seem concerned only with the prevention of exploitation.

Background
P. 4 The author should state which the four moral principles are.
p. 5 The first sentence of first full paragraph “According with…” is incomprehensible.

Discussion
P. 10. It is unclear what the author means by a “fine line” and why the situation she describes is an instance of a fine line. Earlier discussion suggests that the fine line divides acts or situations that are morally acceptable from those that are not. However, both coercion and lack of opportunity seem morally unacceptable. Perhaps the author means, instead, that there is a dilemma: either the subject participates in the trial without giving her adequate informed consent, in which case she is coerced, or she is excluded from the trial, in which case she lacks a crucial opportunity. Furthermore, it is contentious to claim that recruitment without informed consent is always coercive. Several recent articles in bioethics have presented refutations of this view, for instance, Hawkins JS and EJ Emanuel ‘Clarifying Concerns about Coercion’, Hastings Center Report 35 (5), 16-19.
Also: the author often refers to Bioethicist. It is unclear whether this is a particular or typical bioethicist or the journal Bioethicist; consequently, the text is often unclear.

Questionnaire

1. It’s unclear how either set of data establishes the subjects’ quality of informed consent for the reason given above.
2. For each question, the author should say how many subjects answered it and which proportion of subjects gave each answer. It is insufficiently informative merely to list the different answers given.
3. Some of the questions are badly designed. For instance the question “did you read the questionnaire by yourself at the hospital?” requires a “yes” or “no” answer. However, “no” could mean that the subject did not read the questionnaire by him/herself or that he/she did not read it at the hospital.

Minor Essential Revisions

The author should run a spell-check and ask a native English speaker to edit the paper. Here is an (incomplete) sample of the major types of spelling and grammatical errors. The author often uses a comma where a full-stop or semi-colon would be more appropriate. Her use of tense is often inconsistent or incorrect (for instance, the first sentence of Results reads “answer”, but should instead read “answered”, and the last sentence of the questionnaire should have “decide” not “decided”). Some words are missing (e.g. “form” is missing after “consent” in the second sentence of Results on p. 2). Some sentences have extra words that do not fit into the grammatical structure (e.g. it is wholly unclear what the word “intent” is doing in the first sentence of Discussion on p. 3.) The choice of words is sometimes wrong. Example 1: “a giving population” in Discussion, p. 3, instead “a given population”. Example 2: “According with” (p. 5) instead of “according to”. Example 3: P. 9 lines 1 and 4 say “though” where the author clearly means “thought”.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of limited interest

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: No

Declaration of competing interests:

I declare that I have no competing interests.