Reviewer's report

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

Version: 1 Date: 9 March 2006

Reviewer: Catherine M Slack

Reviewer's report:

General
This study describes cancer trial participants' experiences of consent forms.
Investigation of aspects of consent and recommendations for improving consent experiences for volunteers remains a timely and critical ethical concern.
In conclusion, this is a potentially useful study in a critical and timely area.

The authors should respond to the major compulsory revisions before a decision is taken around publication. I recommend that if a revised paper is submitted it should be sent back to reviewers, if this is an option.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

The paper as it stands, however, requires major compulsory revisions before it can be considered for publication. These are as follows:

1. Background. Some review of literature that examines how to improve understanding by enhancing consent forms would be valuable given the scope of the study. See Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: A systematic review. JAMA 2004;292:1593-1601.

2. The aim needs to be revised to consistently represent that the purpose of the study is to assess participants' experiences of consent forms.
   a. At present, the abstract states that the aim is “to evaluate the validity of the consent procedure” (perhaps too broad a statement as process aspects of consent are not examined in any detail); “to evaluate if the informed consent procedure fulfils the purposes that are meant to be achieved (these purposes are not spelled out and the design of the study could not support such an exploration) and that the study “assess(ed) their comprehension of the consent forms” (p2: Abstract). (the study did not assess understanding of trial concepts contained in forms at all!).
   b. Another aim should be added in order to justify the presentation of results of a survey of researchers'/ doctors' opinions of consent.

3. Method:
   a. Evaluation of random selection of consent forms: The author must provide more detail of how this evaluation was done. Given the present detail, this part of the study could not be replicated. It only states that use of technical words, language difficulty, accuracy of translation and “intelligibility” were “qualitatively analysed”. How were technical words defined and recognised? How was language difficulty assessed? To what extent did raters agree with each other? If the methodology cannot be rigorously detailed, perhaps the paper would be strengthened if this section were omitted altogether.
   b. Participants' experiences:
i. It would be helpful if the paper described early on that all persons approached to participate in the survey accepted.

ii. More detail should be provided on the structure of the patients’ survey questionnaire in the text and it should be included as an Appendix. It is currently not clear whether participants in this consent survey answered questions in an open-ended fashion and whether these were qualitatively coded; or whether they selected responses to statements, e.g. “To free the institution and doctors and doctors of responsibility in case something bad happens” (agree — disagree). If this latter format was used, were participants free to select more than one statement or only one? It would not be possible to replicate the study from the information currently provided.

iii. More detail should be provided on the structure of the doctors survey questionnaire in the text and it should be included as an Appendix. Currently it is not clear how questions were posed and in what format doctors were required to answer.

4. A section on scoring and analysis (for both the patient and doctors’ results) must be inserted into the paper. Currently this is absent.

5. Ethics: There should be some discussion of the ethics of this study itself. Currently this is absent. What were participants in this study told about it? How was consent obtained to take part in this consent study and from whom was ethical review obtained?

6. Sample: The paper should describe clearly how many participants took part in this consent survey. There is a discrepancy between the number provided in the text of 55 (page 8) and the number provided in the table of 50.

7. Results:
   a. The narrative text describing the results should describe in an even-handed manner all 10 questions posed to participants. (At present only 4 out of 10 questions are described).
   b. Statements in the narrative text of the results section should be more adequately supported by and linked to specific data. At present there are some ambiguities: E.g., (1) It states that the consent form was too long according to all, however I can only see that 25 participants stated this from the summary table. E.g., (2). It states that those patients who read the consent form thought the explanation from their doctor was clearer, however I cannot see this from the summary table of results. E.g., (3). It states that most patients thought that consent was not needed, whereas I cannot see the data that support this assertion in the summary table of results.
   c. A section in the text must be inserted describing the results of the doctors’ survey in an even-handed manner. At present there are only 3 lines devoted to this. These results should be clearly supported by and linked to actual results presented in the summary table.
   d. SEE TABLES (POINT 12 BELOW)

8. Discussion:
   a. The discussion section should stay closer to the actual results identified in the study and relate these to other empirical investigations of consent experiences, and to conceptual literature on how to improve understanding via enhancing consent forms. At present the author largely makes general objections against compliance with international regulatory requirements for consent that are insensitive to socio-economic and cultural characteristics, as she does in the background section. It would be of more value for readers to hear her thoughts on how the consent forms and processes should respond to the impoverished, poor, largely rural patients in this study and how her data supports such recommendations.
   b. The discussion section should discuss all the major results more critically and consistently. E.g., (1) 50% of participants did not read the consent form! This is an extremely interesting result, given the effort made on translation and the esteem with which forms are held by review and regulatory authorities. E.g., (2) Question 2 elicited the result that every participant was consented by their doctor. What could this say about power differential between the 2 parties and what impact might this have on social desirability responses by the participant? E.g., (3). Questions 5, 6, 9, and 10
elicited answers about how participants made decisions, finding that only the smallest minority decided by themselves. This result could be discussed in the light of some literature on decision-making, or even culture?

c. The author concludes by objecting to “informed consent in the “Western format” however the actual conditions she is objecting to are not clear. If she is objecting to lengthy, complex, boring consent forms that do not promote understanding surely these are as objectionable in a “Western” setting?

9. Recommendations: As alluded to above, currently the author does not make comprehensive and concrete recommendations for how to improve consent forms (and to some extent those limited process features – like consent by the patient’s doctor – that she explores). This is a lost opportunity and would add considerable value to the paper.

10. Abstract: Once the above revisions are undertaken the abstract should be revised.

11. Limitations. Some critical discussion of the limitations of the study would strengthen it, e.g., sample size, generalizability to other trials etc.

12. Tables:

a. Table 2.
   i. This table should be renamed: Summary of results of patient survey.
   ii. There is missing data from the tables, that is, for Question 3 (reviewers numbering) 4, 5, 8, 9, 10 there is no “n” assigned.

b. Table 3:
   i. This table should be renamed: Summary of results of doctor survey.
   ii. The table should provide more detail and substance than it does at present. EG (1). are the readers to believe that all the doctors answered “at the request of sponsors and authorities” to the question “what is the purpose of consent”? What selection of statements did they choose from? Was this result of qualitative coding?
   iii. The table has missing data, that is, for Question 1,2,3,4,5, and 7 there is no “n” assigned.
   iv. The table of results should not contain references. Rather make these points in the discussion.

13. The author should clearly define “coercion” and “exploitation” in the background (p.4, 5) and discussion (p.10)sections, and more clearly delineate the relationship of the these ethical concepts to her study. At present they appear to be used quite loosely and their meaning is not self-evident. Useful definitions can be found in Emanuel E. Ending concerns about undue inducement. Journal of Law Medicine and Ethics 2004; 32:100-105.

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

**Level of interest:** An article whose findings are important to those with closely related research interests

**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.