Reviewer's report

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

Version: 2 Date: 6 June 2006

Reviewer: Catherine M Slack

Reviewer's report:

General
The study outlines deficits with consent in a South American research setting, and many of the results are striking. Furthermore, the author has responded to most of the suggested revisions, and the content has improved.

However, the manuscript still requires an English edit before publication.

In addition, the following changes really should be made to the Editors satisfaction before publication. I am happy to be consulted again if the Editor wishes.

Abstract:
A. Para 3 beginning “Bioethicists actions” Should be rephrased to improve the reader’s understanding.
A. Para 4 under methods: the words “the comprehension and meaning of the” should be deleted so that the sentence reads “To evaluate the IC procedure for patient enrolled etc”
A. Add the words “forms” after “Informed consents” 
A. Results: This section should give examples of the results e.g. “In this study, 66% of patients thought the form was difficult to understand, 49% said they didn’t understand it, and 65% of doctors thought patients couldn’t understand forms. No patient knew the IC was to protect their rights. Consent forms reading level was too high etc.”
A. “A dual figure prevails” needs rewording to clarify
A. Conclusions: “and is institutionally hierarchical” should be explained, rephrased or omitted.

Background: p7. The paper states that the purpose of this paper is to assess participants experiences of the consent form. The authors should add that additional gaols were to get doctors perceptions of the consent procedure and to evaluate consent forms.

Methods: p8 Delete the words “the comprehension and meaning of the” so that the sentence reads “To evaluate the IC procedure for patient enrolled etc”

Results p 14 Are the following 2 sentences contradictory?: “The overall accuracy of the translation was reasonable” versus “The literally (sic) quality of the document was poor as a word by word translation was evident”?

Appendices
The Appendices are not actually the survey instruments but also results “perhaps the authors should clarify that.

Discussion:
In general, the discussion should be re-structured to deal with 1) patient data 2) doctor data and 3) consent forms so that it follows the sequence used in the methods and results sections. This helps the reader to understand the study.

Discussion; p 15 para 3:The sentence “The comprehension of the document decreases even further” should be rephrased or omitted. This study did not assess comprehension of the trial concepts nor its relationship to literacy. The study assessed experiences of forms.

Discussion: p 16: para 1. The 7-line sentence “According with, to had finished it” is not intelligible. It must be re-written. Furthermore, the section “as little as a day after signing the consent most patients could not recall one risk or benefit” is not clear “is this a result of this study? Another
The recommendations are still under developed. Apart from IC should be adapted to the targeted population (how?) and consider social and cultural factors (how?) The author does make a recommendation for how to deal with dual relationship of doctor-researcher (IRBs should consider this). She infers another recommendation (local IRBs should be more involved in IC forms). However it is a pity not to hear her thoughts on how to improve things, after documenting problems with consent.

Conclusions: These are too far removed from the data. Why should health authorities be involved in the consent procedures? These are also unspecified. What specific local criteria should be enforced? Rather the author should stick with a summary of the broad deficits in consent that the study reveals.

Limitations. There is still no limitations section where the author can reflect on the possible short-comings of the research itself; as per previous review. For example, some of the questions in the survey were phrased strangely etc.

Tables: Table 3: last cell has missing data.

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

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

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Discretionary Revisions (which the author can choose to ignore)