Reviewer's report

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

Version: 3 Date: 11 September 2006

Reviewer: Catherine M Slack

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General
The author has responded to most of the suggested revisions from the 6 June review. The English edit has improved the manuscript considerably.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
However, the following revisions should be made.

Appendices
As requested in the previous review, the Appendices are not the actual survey instruments but also results – the author must clarify that.

Table 2: Patients' perceptions:
“Do you know why you were asked to sign an IC” – some additional cells are in Appendix 2 that are not included here.

“After reading the form….improved?”. Figures here do not correspond with figures in Appendix 2.

“Do you have any comments….?”. The figures do not correspond with figures in Appendix 2.

Table 3: Doctors responses:
“Which of the following…the IC?” The figures are out of line.

“Do you receive any type of compensation from the sponsor company?”. Additional cells in Appendix 3 are missing here.

Abstract:
· Under methods: the last sentence should read “The patients’ experience of the IC and doctors’ assessment of the IC was evaluated in this study”.
· Results: As requested in the previous review, this section should give examples of the results of the patient and doctor survey, 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”.

Results:
p 10 reads “after signing the consent, only 2 patients knew what the document explained about treatment risks and benefits”. Where is this data on Table 2?

p11 reads “(Doctors) knowledge of the Mexican General health Law IC requirement was only inferred”. What does this mean?

p11 also reads “Most of them (doctors) had …few times (if ever) carefully read the consent form”. Where is this data on the Tables of results or questionnaire?

Discussion:

On page 14 the sentence “This work strongly contends”…should read “This work strongly contends that presenting and signing a consent form is not enough for the study to be ethical etc…..”
Page 16 reads “The level of perceptions….” This sentence should read “The perceptions of patients in this study about the IC form are not surprising.

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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)

B DISCETIONARY REVISIONS

Methods:
p7 Delete the word “qualitative” from the first sentence.

Page 8 “a visual numerical scale was used” by who? Insert the persons who scored the ICs. If it was only one person, state that 2 raters were not used and there is no inter-rater reliability data.

Results:

P12 reads “although questions were not made about moral principles and ethical behaviour, all of the responding doctors thought that the survey put in doubt their integrity as physicians (these arguments were made verbally, no written complaint was made”. If this observation cannot be supported by written data, the author should omit this or soften the claim.

Discussion

As in the previous review, 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.

Page 16 reads “…if the legitimacy of the IC is focussed on this issue, then few patients attending this institution would be able to give a valid consent”. This is too broad an assertion. Rather focus on the key results for this sample (majority thought it was too long, half said they did not understand it)…

Conclusions

The recommendations are better developed in the conclusions section. The author could also consider developing short-form information sheets (e.g. 2 pages) in line with data that short forms may enhance understanding (c.f. Flory and Emanuel, 2004) and extended contact with a trained research team member (ibid) preferably one with a similar socio-cultural background and worldview to volunteers (Lindegger & Richter, 2000).


Flory J, Emanuel E. Interventions to improve research participants’ understanding in informed consent for research: A systematic review. JAMA 2004;292:1593-1601.