Author's response to reviews

Title: An eight-year follow-up national study of medical school and general hospital ethics committees in Japan

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Author's response to reviews: see over
Dear Dr. Slowther,

Thank you for your review and suggestions. Your commentary was once again helpful to the preparation of our manuscript for the Journal. Please find below an explanation of our revisions.

Best regards,

Akira Akabayashi, MD, PhD

Reviewer’s comments are italicized below.

I still find parts of this paper confusing because of the conflation of research ethics review and the clinical aspect of the ethics committees. The authors have now made it clear that ethics committees in Japanese hospitals and Universities have combined research and clinical activities. However the introduction still sets the scene as if research ethics review is the major area to be considered in this study. As a key comparative activity looked at in the study is the development of a clinical ethical guideline, that of blood transfusion for Jehovah’s witnesses, this creates confusion for the reader. I would suggest that the introduction is re-written to separate out the research protocol review and clinical support activities of ethics committees even more clearly. Thus the initial background could as now stress the importance of the development of research ethics review and committees for this, with reference to the declaration of Helsinki. A separate paragraph could then explain that in many countries separate ethics committees had developed to consider ethical issues in clinical care and institutional policy making (for example the US and the UK). A third paragraph could then set out the situation in Japan, emphasising the combined role of Japanese ethics committees in Medical Schools and hospitals. It would be helpful to know what differences there are between these two types of committee. DO medical school ethics committees provide policies or advice to teaching hospitals and hospital ethics committees provide policy and advice to non teaching hospitals? These suggestions would incorporate the current background that the authors have given but clarify the situation both internationally and in Japan.

We have re-written the Introduction according to your comments. In particular, we have revised the first three paragraphs to better introduce the overall background of our study as you had suggested. Additional references have also been supplemented.

I am still not clear what justification the authors have for using the existence of a policy on blood transfusion in Jehovah’s witnesses as a marker for either committee activity or committee or how well a committee functions. Can the authors explain why this is seen as indicating adequate functioning of a committee?

We agree that the use of an ethical guideline for dealing with Jehovah’s Witnesses may not be a valid index for adequate functioning of a committee. We have revised both the methods and discussion sections to indicate that this serves as a non-representative index, yet nonetheless as a possible index.

“We chose to use number four because the existence of ethical guidelines for dealing with Jehovah’s Witnesses in Japan can serve as a possible indicator of EC functionality.” (Methods, Instruments)

Fourth, the use of an ethical guideline for dealing with Jehovah’s Witnesses may not serve as a valid index for adequate functioning of a committee. Further research is needed in order to develop a scale to assess the efficacy of functioning of a committee. (Discussion, Limitations)

Would the authors like to comment on why they think medical school ethics committees are more active than hospital ethics committees. This would be an interesting discussion point.
For the international reader, we agree that this is an interesting point. We have elaborated on the discussion of this disparity as shown below.

“We surmise that this difference is because medical school ECs tend to be more active than hospital ECs in developing policy. One possible explanation for this disparity is that medical school ECs generally function as a leader in developing ethical policy in Japan. Looking deeper, this may be related to the hierarchy of Japan’s medical world in which universities hold the mainstay of power.”

(Discussion)

Once again thank you for your insightful commentary and we hope the revised manuscript is now ready for publication in the Journal.