Author's response to reviews

Title: 'Relief of oppression': An organizing principle for researchers' obligations to participants in observational studies in the developing world

Authors:

James V Lavery (jim.lavery@utoronto.ca)
Sunita VS Bandewar (sunita.bandewar@utoronto.ca)
Joshua Kimani (jkimani@csrtkenya.org)
Ross EG Upshur (ross.upshur@utoronto.ca)
Frances A Plummer (Frank_Plummer@phac-aspc.gc.ca)
Peter A Singer (peter.singer@mrcglobal.org)

Version: 2 Date: 23 April 2010

Author's response to reviews: see over
April 23, 2010

Editorial Team
BMC Public Health

Dear Sir or Madam:

Re: MS: 1312154593408159

'Relief of oppression': An organizing principle for researchers' obligations to participants in observational studies in the developing world. James V Lavery, Sunita Bandewar, Joshua Kimani, Ross EG Upshur, Frances A Plummer and Peter A Singer

Thank you for sending us these very helpful reviews of our manuscript. We have now revised the paper according to the reviewers' suggestions and the corresponding changes are reflected in the attached manuscript in “Track Changes”. Here is a quick overview of the changes. For each reviewer's suggested revisions we specify what changes we have made and provide our rationale, where necessary.

Referee 1: Vural Ozdemir

1. As a concept, “relief of oppression” will populate the “barren middle ground” in the “menu” of principles and concepts to evaluate the researchers' responsibilities and benefit sharing in long term observational studies. This point can be emphasized further – that there is a need for a range/menu of principles to evaluate the benefit sharing and the responsibilities of researchers in a context of global health.

Although we agree with the reviewer's intuition here, we feel that further elaboration of this point would actually require considerable detail, and therefore a good deal more writing. We think this would serve to de-focus our argument. As a result, we have decided not to elaborate further in this manuscript.

2. One or two other potential (but brief) examples of the conceivable application contexts (e.g., other than for STD observational studies) for the relief of oppression principle can help guide future research and applications of this principle.

On the first full paragraph of p. 17, we have added two more examples of contexts that we believe relief of oppression might have particular relevance—childhood nutrition/malnutrition research and environmental health studies. In both contexts disease burden disproportionately affects the
poor and there is known to be a wide range of oppressive forces at work in these contexts.

3. The authors correctly suggest that sometimes well-meaning activist attempts can do more harm than good, when there are no practical guidelines to evaluate exploitation (e.g., when sex workers abruptly quit work in the absence of a long term safe employment alternative, creating a vacuum that is not sustainable). This point can be emphasized further.

As for comment #1, above, we agree with the reviewer that this is an important point. However, for similar reasons, we are concerned that elaboration would de-focus the paper. The example we use in the paper, and the one that the reviewer refers to, above, is a clear and potent illustration of the hazards, AND is tightly integrated into the case study we report. Introducing another example from another context might be confusing. As a result, we have not provided any further elaboration on this point.

4. LMIC abbreviation is not defined early in the text (low and middle income countries).

This has been corrected throughout the manuscript.

5. In the acknowledgements there is a typographical error. “We are grateful to…”

The acknowledgements have been corrected.

6. Spelling of “moreso” in the text should be “more so”.

Change has been made

Referee 2:

Referee #2 did not itemize specific comments in his commentary. We believe there are 3 main points that arise from this commentary that we have tried to address constructively and we address each of these, below.

1. Mention the “Tuskegee” trial as a way of grounding the discussion in some of the historical injustices that have taken place in the context of observational research.

In the second paragraph of the Background section, beginning on p. 5, we provide a brief introduction to the “Tuskegee” trial and highlight the fact that the trial exacerbated the participants’ oppression, rather than providing any relief. We then cite the seminal paper by Marcia Angell, then editor of the New England Journal of Medicine, which drew the analogy between the HIV short-course AZT placebo-controlled trials in the mid-1990s, and thereby launched the debate that the reviewer refers to in his comments.
2. The reviewer emphasizes in his comments that our proposal would benefit from some elaboration of the details of how relief of oppression would be applied by investigators in the field, beyond the example of the Majengo cohort.

We feel that one of the key elements that makes our paper novel and innovative is the recognition that the application of a concept such as “relief of oppression” cannot be predicted clearly in advance, and therefore a strategy is necessary to account for how the details of application of the approach can be discovered and refined. We have introduced the analogy with harm reduction precisely for the reasons the reviewer raises.

We have added some language, beginning on the bottom of p. 16, to emphasize this point further.

3. The reviewer raises the same issue as was raised by Reviewer #1 (comment #2, above). Our response to that comment describes our response and changes in the manuscript.

Thank you very much for these very helpful reviews. I hope our responses provide adequate clarification of these important points. As well, we hope our corresponding revisions to the manuscript make it acceptable for publication.

Best wishes,

Jim Lavery, Ph.D.
Centre for Research on Inner City Health and
Centre for Global Health Research
Keenan Research Centre in the
Li Ka Shing Knowledge Institute of
St. Michael’s Hospital
Assistant Professor
Dalla Lana School of Public Health and
Joint Centre for Bioethics
University of Toronto
70 Richmond St. E., 4th Floor
Toronto, Ontario
M5B 1W6

E-mail: jim.lavery@utoronto.ca

Assistant: Jennifer Earley