Author's response to reviews

Title: Consent for use of personal information for health research: Do people with potentially stigmatizing health conditions and the general public differ in their opinions?

Authors:

Donald J Willison (willison@mcmaster.ca)
Valerie Steeves (vsteeves@uottawa.ca)
Cathy Charles (charlesc@mcmaster.ca)
Lisa Schwartz (schwar@mcmaster.ca)
Jennifer Ranford (ranfoj@mcmaster.ca)
Gina Agarwal (agarg@mcmaster.ca)
Ji Cheng (chengj2@mcmaster.ca)
Lehana Thabane (thabanl@mcmaster.ca)

Version: 4 Date: 10 June 2009

Author's response to reviews: see over
We have had an opportunity to consider the reviewers’ comments and make amendments to our manuscript accordingly. Reviewers 1 through 3 had essentially no comments. Below please find the response to Reviewer 4’s comments to the statistical methods. We trust that these revisions will satisfy the suggestions of the reviewers, which we felt to be very constructive.

**REVIEWER’S COMMENT REGARDING USE OF LINEAR REGRESSION**

Use of linear regression to model the ordered categorical consent choice outcome variable might be questioned, since the measure is not inherently intervally-scaled, however, the authors address this satisfactorily by reference to earlier work which showed equivalence. However, the decision to use linear regression rather than multinomial logistic or ordinal regression has consequences for the interpretation of results. As a linear score, the magnitude of the reported effect sizes (Table 2) must be interpreted as fractions of a “step” on the ordinal scale from “no concern” to “complete refusal”. The authors fail to make this connection anywhere in this manuscript.

**AUTHORS’ RESPONSE:**

We agree that use of linear regression generally requires an interpretation of reported effect sizes as fractions of a step on the (ordinal) outcome variable – in our case, consent choice. Our intention with Table 2, though, was to tease out the relative impact of health condition vs. attitudes (disclosure concern and perception of medical benefits) on the outcome variable (consent choice). This was the rationale for comparing reduced models 1 and 2 with the full model through an increment to R² analysis. We deliberately avoided the quantitative interpretation of fractions of a step-function in our outcome variable because our data are ordinal and not interval and because this was not our focus.

**REVIEWER’S COMMENT RE: NON-LINEAR PATTERN OF COEFFICIENTS WITHIN HEALTH CONDITION.**

The reviewer suggests we comment to the non-linear pattern of coefficients within health condition.

**AUTHORS’ RESPONSE:**

Our thanks to the reviewer for this suggestion. This comment seems to assume that we had formally determined an ordinal relationship across the health conditions. While we recognized beforehand that hypertension and diabetes were relatively low in stigma and that HIV and alcoholism were likely higher in stigma, we did not assume strict ordinality across health conditions. We have clarified this point in the first paragraph of the Discussion section, under “Chief Findings”.

**REVIEWER’S COMMENT RE: INTERPRETATION OF THE CONFIDENCE INTERVAL WIDTHS IN TABLE 2**

The reviewer suggests that interpretation of the confidence interval (CI) widths from Table 2 is necessary.
AUTHORS' RESPONSE:

This is a reasonable suggestion. It is unclear whether the CIs we are observing would be policy relevant, as we have no priors. Intuitively, though, we sense that the larger confidence intervals across health conditions may not represent sizes that would be clinically important or policy relevant. That is, a 0.4 upper CI for HIV represents less than a half-step more stringent a consent choice – e.g. from a broad opt-in consent to a project-specific consent or from a notice-with-opt-out system to a broad opt-in consent. The challenge is the ordinal (i.e. non-interval) nature of the outcome variable. We have added a sentence on line 9 of the first paragraph in the Discussion section to indicate that we felt the bounds of the CIs did not appear to be policy relevant.

We also note that, initially, we graphed the consent choices across scenarios for each health condition and found very similar consent choice profiles across health conditions. That is why we pooled the results across health conditions (described on page 8 in the first paragraph under “Consent choice”).

Finally, we note that the point estimates of the parameters are small and in the direction anticipated: most were negative (i.e. in the direction of a more permissive consent choice). This was anticipated because it is consistent with findings in health economics that those with health conditions (e.g. paraplegia) regard their quality of life more favourably than do those who imagine they have that health condition. Similarly, one could imagine that, as one experiences a chronic illness, he/she may become more relaxed about use of that information for research. With the exception of diabetes, these point estimates are also closely correlated with the Disclosure Concern scores that are plotted in the radar graph in Figure 2. The slightly positive consent choice parameter for HIV/AIDS makes sense.