Author's response to reviews

Title: Communicating serum chemical concentrations to study participants: follow up survey

Authors:

  Alexandra J Buck (ajbuck@buffalo.edu)
  John E Vena (jvena@uga.edu)
  Bridget M McGuinness (bridget.m.mcguinness@gmail.com)
  Maureen A Cooney (cooneyma@mail.nih.gov)
  Germaine M Louis (louisg@mail.nih.gov)

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Author's response to reviews: see over
Dear Editor:

Enclosed please find our revised paper entitled *Communicating Individual Chemical Exposures to Study Participants* that we are submitting for further consideration by *Environmental Health*. We believe that this revision is responsive to the reviewers’ comments. Please note that reviewer #2 challenged our language regarding the very limited empirical data for communicating individual results and cited references for our consideration. In fact, some of these authors state the same conclusion – noticeable absence of published data regarding strategies for communicating individual exposures as does the 2006 NAS report now referenced in the paper. Similarly, our comment about conflicting views on the part of IRBs was also noted by some of the authors the reviewer suggested we cite supporting our experience with numerous IRBs. The same corroboration arises in the suggested references regarding IRBs mixed decisions regarding whether or not to communicate individual values when information about exposure and health outcomes is uncertain at best (references). Also of note is our relatively large sample size in relation to the earlier studies that have attempted to evaluate communicating individual results. Moreover, our initiative was restricted to actual study participants for whom toxicologic results were sent. In sum, we believe our paper is correctly written and a contribution to the literature while underscoring the importance of giving back.

As stated earlier, this paper represents original research and no aspect of it has been previously presented nor is any part under review elsewhere. All authors have participated in either the design, implementation, analysis and/or writing of this paper, all take public responsibility for its content and all approve its submission to *Environmental Health*. Please do not hesitate to contact us if you should have any further questions.

As requested, a point-by-point response to the two reviewers follows.

Respectfully submitted,

Maureen A. Cooney, PhD, MPH
Response to Reviewer #1 (J. Collins)

1. We note that we sent a two-page letter on page 10. The PCB congeners selected were a joint decision with the trans-disciplinary members of the study team, given their potential health concerns (i.e., lead) and the availability of data for the comparison groups. We spent considerable time discussing which congeners to report back and decided upon those with some evidence of health effects in the literature and of concern for our geographic area, and also congeners with concentrations reported for other populations including the U.S NHANES population and other fish eating samples. We also provided the sum as a measure of overall PCB exposure quantified. We note this further on pages 10-11.

2. There was no added communication around PCB 118 or any other congener, given the absence of known adverse effects at a specific concentration. We complied with the recommendation of our health department colleagues in keeping lead the contaminant with a health alert. None of our study participants had lead exposures at the health alert level. In fact, mean concentrations for lead was relatively low for the entire cohort as noted on page 11.

3. As shown in Table 1, we had a column with the heading health based concentration denoting a concentration with an established health alert. We listed that value only for lead as none of the other columns have established values.

4. Serum PCB and DDE concentrations were generally similar to those for women as reported in NHANES III, but lower than that for fish eaters. Only six women had one or more individual concentrations higher than that reported for the U.S. referent population as noted on page 11.

5. In this particular letter communicating results, we did not mention health benefits of fish consumption. Our cohort comprised reproductive aged women for whom fish consumption from the surrounding Great Lake water bodies or tributaries is strictly limited or prohibited depending upon the species.

6. We more completely describe the letter on pages 10-11 and include the essence of the second page, which contained the exposure data on Table 1. We do not include the letter, since the first page was personalized to each woman.

7. We obtained a standardized amount of blood from women and understand that it was sufficient for analysis. We understand the reviewer’s important point about LOD, though we believe sample volume was not the issue. The decision to include this sentence stemmed from final agreement amongst the study’s trans-disciplinary research team as noted on page 11.
Response to Reviewer #2 (P. Brown)

1. We agree with the reviewer that few investigators report back for a number of reasons. We have further developed our background to reflect the suggested papers, many of which emphasize the points we previously noted – tendency to report aggregate rather than individual data, limited empirical study, conflicting IRB positions. See revised introduction.

2. We have further described our letters (see pages 10-11) and included the data table from the letters in table 1. We agree that comprehension is important even for our cohort that comprises mostly college-educated women.

3. While we agree that in-person venues for reporting exposures may be ideal, we had no funding to do so. Moreover, women resided within a 16-county area along Lakes Erie and Ontario, which is a considerable distance. We agree that researchers should ideally have funds for communicating study results.

4. As noted in some of the suggested papers for inclusions, IRBs vary in terms of reporting back. While we do not have specific citations (if there are such we'd appreciate this information), our current experience conducting environmental studies within three states is one of an increasing trend to report back, but by no means is required by all research institutions.

5. We have revised our text to make it clear we meant aggregate versus individual data. See our revised text on page 4.

6. We have edited our comment regarding corporate requirements for a communication plan. However, we respectfully disagree with the reviewer's comment that it should not be mentioned. Efforts to bring researchers, communities and corporate entities together in seeking answers have been previously discussed and efforts should continue. Some of the earlier reporting back was in occupational setting underscoring the role of many corporate entities in moving in this direction. See pages 4-5.

7. We note the reason for reporting back individual exposures, viz., it was planned from the design of the NYSACS, the overall cohort from which the prospective pregnancy cohort was selected. At the time, communicating individual concentrations was highly controversial and we had to work to achieve consensus within our trans-disciplinary research group, with the IRB and collaborators from the State Health Department. We note this on page 7. As a point of clarification, women participated in the cohort for up to 12-months while at risk for pregnancy. Subsequently, a few years later women and their offspring re-enrolled and participated in 12 and 24-month developmental assessments of the children. The cohort has not been continuously ongoing, largely a function of limited funded.
8. We agree that personal interaction may be best for communicating results. However, other methods such as individual letters have been used including by NHANES (the largest communication plan that we are aware of). What is important is the development of various communication tools that fit funding options and respect study participants’ preferences as not all participants would opt for in-person venues. Randomized intervention trials aimed at the formal evaluation of approaches (and comprehension) would be most helpful to researchers and participating communities.

9. We agree it is hard to fully evaluate the effect of the communication plan regarding comprehension and concern. What is indisputable, however, is that the researchers and study coordinator were long known to the study participants and that the women had numerous options for contacting the research team. The fact that the women completed a final questionnaire but did not note any questions would suggest that the women were at the very least not frightened or concerned by the letters. In fairness, some study participants may be intimidated by an in-person approach and simply give the interviewer the feedback he/she thinks they want. A randomized trial is one way to empirically evaluate the effectiveness of methods for reporting back.

10. We were no able to follow up interviewees nor were we able to assess if women sought information elsewhere, given the completion of the study and no additional funds for follow up.

11. We have noted why we gave women their concentrations (even if after up to 10 years) on page 8.

12. We are not able to state what the women thought as we did not re-contact them following receipt of the information. As we stated, our IRB approved one final contact with women (communication of results and the questionnaire) given their involvement to date. One future option is to design and implement a pre-post-test design if comprehension is to be empirically evaluated. We respectfully disagree with the comment that investigators cannot give exposure data back after long periods of time. If there are such published data, we would welcome the citations and revise our work accordingly.

13. For clarification purposes as noted in our revised paper, this is not a theoretical paper, per se, addressing conceptual paradigms and the ethical interpretation of reporting back as articulated in the papers suggested for citation. As we stated, our intent from the design of the cohort was to give concentrations back – women were told this, though we said it would take years in part given how long laboratory analysis took. We believe this approach complies with research ethics. Our research focus is much narrower, which is to describe what we did in an empirical fashion for this population based prospective pregnancy cohort, and to allow the reader to evaluate the approach further. As many of the suggested references state, most investigators do not communicate individual exposure data for whatever reason.
Our intent is to demonstrate it can be done even when less than idea. The absence of fear or concern as measured by no contact from the study participants despite their relationship with us would suggest at the very least the cohort was not harmed. We have done our best
to deliver on behalf of our cohort, and this approach may or may not work for other researchers but it is an opportunity to evaluate options. The suggested citations have been incorporated throughout the paper.