

Author's response to reviews

Title: Toxic Ignorance and Right-to-Know in Biomonitoring Results Communication: A Survey of Scientists and Study Participants

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David Ozonoff, MD, M.P.H.
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Dear Dr. Ozonoff:

I am pleased to submit revisions to our manuscript (MS: 1785140101235612). We appreciate the reviewers' and the editors' helpful comments and have outlined below our specific responses to their feedback. Reviewer responses have been cut and pasted verbatim below.

Reviewer 1 (J. Sass): Overall, Dr. Sass indicated that our manuscript was an excellent paper, "well-written and well-conducted." She did not recommend any specific revisions.

Reviewer 2 (K. Van Damme): Dr. Van Damme was supportive of publishing our manuscript and made several concrete suggestions for improving the paper, which we address below (We have italicized Dr. Van Damme's comments).

the structure of the paper announced on page 6 does not reflect what follows. It would be good to verify this and possibly revise the whole paragraph.

We have re-written this paragraph (which now appears on Page 7) to accurately reflect the current structure of the paper.

An important statement in this paper lays is the one made on communication of results under the heading "Addressing varying levels of literacy". Indeed, good communication is not easy and requires lots of effort and empathy of the communicator. Good communication on uncertainties is even more difficult. But it must be done, and one has the duty to strive for the best possible communication in every individual case: respectful, correct, accessible.

We agree with Dr. Van Damme and believe that the statements in our paper in this section concur with her comments on this issue.

..one should clearly state that the paper only deals with 'exposure' bio-monitoring, not with adverse health effects or susceptibility tests. The quoting [12, 13] on page 4 is confusing in that respect! Also, on the next page, reference is made on the advances in molecular biology which "have made these techniques more sensitive, specific and biologically relevant" a statement followed by a few examples in the next paragraph which have nothing to do with the statement. A more unequivocal definition should be given on which kind of bio-monitoring is at stake in the paper.

Dr. Van Damme is correct and we have clarified this section to explicitly state that this paper focuses on exposure biomonitoring (See Page 5). We rewrote the sentence as follows:

“Although we focus on exposure biomonitoring throughout, parallel issues are raised by other personal exposure assessment methods, such as dust and air samples taken from an individual’s home.”

The paper refers de facto (my suggestion is to say it explicitly) to a USA context.

We have added text on Page 5 to clarify that our paper and survey are specific to the United States:

“This paper heeds NAS’s call for additional research that elucidates new approaches for addressing the scientific and ethical challenges of biomonitoring results communication in the United States.”

Since the right-to-know still seems to be an issue of controversy in the USA, it is not surprising that the titles given in the paper to the ‘Frameworks for Considering the issue of Report-back’ seem to reflect both the ‘struggle’ and the confusion on this right-to-know principle. The titles are:

- 1) Clinical ethics*
- 2) Community based participatory research*
- 3) Citizen science ‘data judo’*

These titles are confusing, since they are not at the same level of consideration. Also the comments are not. This may give the impression that the authors are fully involved in the ‘struggle’. Given the actual content of these chapters, more logical titles might be:

- 1) communication with a therapeutic goal or with an immediate individual preventive goal*
- 2) communication with an ideological goal*
- 3) communication with an immediate political or regulatory goal*

Such a subdivision (which might require some reformulation of the texts) might make the arguments more useful for a debate on the right-to-know principle, and they might constitute a better introduction to the proposals in the second part of the paper. But even without such changes, it is an interesting paper because it is illustrative of ongoing controversies on the issue in the USA.

We did not completely understand Dr. Van Damme’s comment regarding the titles for the three frameworks that our survey found scientists use when deciding whether and how to communicate individual-level biomonitoring results. We have modified this section a bit to clarify our points at the beginning of this section, but have decided to stick with our original titles. Dr. Van Damme is right in that these frameworks illustrate the tensions within the U.S. about how to balance right-to-know within the context of scientific uncertainty regarding the health implications of biomonitoring results.

We moved the first paragraph of this section to the end of the paper because we felt that it was distracting from our focus on the discussion of these three contrasting frameworks for results communication (Page 13). We also simplified the title of this section to clarify its contents. It now reads:

“Frameworks for Communicating Biomonitoring Results.”

We have also added a table to highlight the main distinctions between these three frameworks. This modification was also suggested by the editors (See Table 1, which appears at the end of the manuscript).

Page 15, quoting [41]: “Communicating risks to affected individuals should be an integral part of any community based project. It is ethical to return information to the owner of that information.” This is contrasting with the statement that “The CBPR approach must be strategic, however, since this framework raises potential conflicts of community versus individual right-to-know.” This is well explained, but lacks the explicit conclusion that ‘ownership’ of the individual as a principle, is incompatible with that ‘strategy’. Unfortunately, this comment is not made. It might be illustrative of the existing confusion on the right-to-know principle. ‘Ownership’ looks like a superficial ideological argument (used in favour of the right-to-know) that can probably not withstand the proof of a judicial evaluation in this case.

Although we concur with Dr. Van Damme’s observation regarding the apparent contradiction between the notion of individual “ownership” of information and the duty to report back versus the potentially deleterious impacts on communities of this type of results communication, we believe that this is an important contradiction to emphasize in the paper in this section. Indeed, the study we cited in this section raises this dilemma explicitly and suggests that this is not merely a superficial ideological argument in favor of right-to-know, but has been an essential tenet in some CBPR studies for developing communication protocols for biomonitoring results. However, we believe that this position poses some potential pitfalls related to community impacts, such as collective stigmatization. We explicitly suggest an effective way to address this tension: “These potential pitfalls of report-back and right-to-know can be proactively addressed if researchers purposefully develop protocols and communication strategies in partnership with study communities prior to the initiation of a biomonitoring project” [Page 17]. We also do not want to add a discussion of judicial evaluation of this question, since this complex issue is beyond the scope of this paper and is actually something we are currently analyzing for another project.

Sometimes, foggy wording hides the key ‘communication’ problem as addressed in this paper. An example: Repeatedly, the word ‘meaningful’ or ‘meaning’ is used to state what the nature of a communication on study participants exposure level(s) should be. E.g. page 14 “(...)comparing individual results with information on national average exposures in the general population provide one way for individuals to understand the meaning of their individual biomonitoring results” and page 15: “(..) could be meaningfully compared(..) Meaningful in relation to which objective? This is not clearly explained, while it should be done at the very same place. For instance: it favours alertness on possible sources of exposure among individuals or populations, so that further increasing of body burden could be prevented. But not necessarily: meaningful indicator of an increased risk for a well known adverse health effect, since we just might not know. This is important, because both ways of being ‘meaningful’ may require very different ethical considerations.

We agree with Dr. Van Damme that the idea of giving “meaning” to biomonitoring results can have different objectives (e.g. highlighting potential sources that could help reduce exposures, or comparing to a regulatory benchmark that may highlight potential health risks). We have modified the wording on these pages to clarify what we mean in both of these sections. On page 15 we modified the following paragraph to read:

“While health-based benchmarks are unavailable for most of the chemicals tested in humans, population surveillance biomonitoring programs that have emerged over the last 10 years provide useful comparison data for individual biomonitoring results. Indeed, scientists involved in an epidemiological cohort study of the developmental effects of pesticide exposures explained that the research team began by only reporting aggregate biomonitoring results, but subsequently reported individual-level results because exposure levels could be compared to the national average levels

provided by the CDC's biomonitoring information [19]. Although these comparisons are useful, they often do not help elucidate potential exposure pathways and sources nor do they relate exposures to levels that have been associated with health effects."

At several occasions the involvement of the community is addressed. E.g. page 17. Unfortunately, nowhere the question is asked: who represents the community? Who will decide, how, and on which grounds, on who will represent the community? We abstain from further considerations on this issue in our comment, but the authors cannot abstain from at least [sic] raising the question, even without necessarily providing elements to the answer.

We concur that the question of community representation is an important one. We added text to this section on page 17:

"These potential pitfalls of report-back and right-to-know can be proactively addressed if researchers purposefully develop protocols and communication strategies in partnership with study communities prior to the initiation of a biomonitoring project [30, 49]. Key to this process is a collective understanding about who represents the interests of study communities and how their issues can be effectively deliberated and incorporated into protocol development."

On page 9, using ref [35] the four ethical principles, known as the Georgetown paradigm are quoted and apparently 'interpreted' by the authors. Autonomy is used by the authors as the reference value for the right-to-know, omitting it can also be the reference value for the right-not-to-know. Not only the 'autonomy' but also the 'justice' principle is said to weigh in favour of reporting individual results to study participants. This seems a completely arbitrary and subjective interpretation: for some participants, communicating to a series of participants—in accordance with their autonomous will—that their heavy metals body burden is elevated may become information that will see the daylight and make other people in the area suffering for instance from lost real estate (example taken from the paper page 16 and 17). They might not consider this as 'justice'. And what is the gain for the autonomy of the individual if the 'meaning' of the result is not clear? It seems that the argument of the autonomy is put forward here because it is part of a struggle against the opponents of the right-to-know. It is not [made] clear why acceptance of the right-to-know principle would need the gain in autonomy as an argument. Also the jump from 'beneficence' to 'democracy' is quite acrobatic. We think it is preferable to leave the Georgetown paradigm for what it was initially intended to be used for: clinical medicine. The set of principles as formulated in the Georgetown paradigm does not easily fit with the need for orienting the ethical conduct in public health research.

We have modified the text in this section to clarify that autonomy includes the right-to-know and the right-not-to-know. We have also changed the language associated with beneficence to delete the association with democracy. We disagree with the reviewers' argument that the Belmont principles were primarily aimed for research in clinical medicine. These principles are applied by US IRBs to review all kinds of public health research and therefore are relevant for exposure studies. We have highlighted in the text that despite the existence of these principles, there is a paucity of guidance to address the unique communication challenges of biomonitoring studies.

"Few precedents exist for reporting biomonitoring data to individuals when there is little information for interpreting health implications. The first discussion of this issue was the Department of Health, Education and Welfare's 1979 Belmont Report [35]. The report's guidelines for protecting human subjects in research rest on four principles: autonomy, which includes the right-to-know (or the right-not-to-know) as a basis for self-determination in acting on research results; beneficence and non-maleficence, which together encompass the researcher's responsibility to maximize good and minimize harm; and justice, which refers to the distribution of benefits and harm [35]." (Page 10).

This brings us the criticism towards the IRB's: the authors did not seriously consider in their criticism the argument that the freedom to communicate the individual results to the media might interfere with the freedom of others who are facing the same exposures and might subsequently be perceived as having the same body burden. Individual results may indeed be good indicators on the average body burden of the population to which these individuals belong. If my understanding of the paper is correct, the IRB's use confidentiality as an argument to prevent this to happen. It would be nice to find in the proposals a clear statement on what confidentiality is about and should not be about, according to the authors.

We don't think that any one individual sharing their personal information with the media inherently jeopardizes the confidentiality of others. The right-to-know in biomonitoring studies includes the right to share that information, just as much as a person with a disease discovered in a community health survey would have that right. We do agree that if all participants in a "data judo" study know each other, that they should guarantee that they will not divulge the identity of others to anyone. It appears that Dr. Van Damme is also concerned with the potential for an individual's results to be good indicators of the local population average. We actually find significant variation in our own study. But even if the body or household burden of a participant who went public was such an indicator, that doesn't appear to us as any violation.

In terms of Dr. Van Damme's desire for a "clear statement on what confidentiality is about and should not be about," we offer two responses: First, on page 24, we already wrote:

"Most interviewees acknowledged the importance of having community representatives involved in the decision of whether and how to report individual and aggregate study results. They felt that it should be the community's decision whether individuals receive their own data, especially in situations when studies included participants whose illness was potentially linked to a substance under study."

We believe that text provides part of the answer. Second, we clarified the paragraph on page 31 and added in the fifth subsection of our results, (on page 31), a clear statement about IRB confidentiality standards:

"An IRB's duty to protect confidentiality ensures that personal information is not released without a participant's explicit desire and instruction. Nevertheless, as with any health information, a person should be free to share their information with others, as long as they do not consciously violate other people's desire to not share their data."

Page 3: "(...) democratic scientific practice." Democracy means: the people decide. On what exactly? By majority voting? Maybe the authors do mean: participatory scientific practice?

We have changed the language in the abstract as suggested.

Page 6: "This makes it imperative to address ethical challenges of biomonitoring". I would prefer: "This makes it imperative to address some specific ethical challenges of biomonitoring", since there are reasons for addressing ethical challenges in biomonitoring practices which have nothing to do with the lack of toxicological or epidemiologic evidence or with the lack of regulatory benchmarks.

We have changed the language in this sentence as suggested.

Page 6: "(...) to communicate information about the effect of low level chemical exposures on health (...)" This is the first time that reference is made to 'low levels' of exposure. This should be done earlier in the paper.

We removed the word low from this section and also wanted to point out that we first address this issue on Page 5 or the second page of the Background section with the following sentence:

“These efforts rest on newly developed analytical methods that detect ever lower concentrations of an increasing number of chemicals for which animal and cell studies show troubling biological effects, but human exposure levels, exposure sources, health effects, and exposure reduction strategies are not yet well understood.”

Page 8: Paragraph starting with “New ethical dilemmas (..)” It would be good to distinct in that paragraph the difficulty to identify any possible effect and the additional difficulty to establish a dose-response relationship for that effect.

We have reworded this sentence on Page 9: “New ethical dilemmas have emerged regarding the reporting of exposure data, especially since information about health outcomes and dose-response relationships is uncertain or not available”

Page 29, last sentence: is the sentence grammatically OK?

We have split this long sentence into two sentences to make it more readable:

“Scientists and community members involved in these studies support community right-to-know; however, this work also poses a significant challenge since exposure reduction strategies are extremely difficult to employ. In the case of the Inuit, efforts to reduce pollutant levels in marine mammals require international political action and a long time horizon, given the environmental persistence of some contaminants [66, 67].”

Regarding comments from the editors:

We have re-titled the paper to conform to your journal’s preferred title format. The new title is: *Toxic Ignorance and Right-to-Know in Biomonitoring Results Communication: A Survey of Scientists and Study Participants*. We have also separated our Results and Discussion sections and have worked to trim back text throughout the manuscript.

On the title page, we organized the email list in sentence structure separating the initials and emails with a semi-colon.

We began the section titled "Background" on the following page after the Abstract (page 4). We have clarified that the section entitled “Central Issues in Reporting Exposure Data to Individuals and Communities” (page 22) is a subsection of our Results.

We have listed the abbreviations in sentence format in a single paragraph separating the terms with a semi-colon (Page 34)...

We have developed a table outlining the three frameworks applied by scientists for biomonitoring results communication. This is now Table 1 and appears at the end of the manuscript.

We added a reference to Altman et al., 2008, a paper of ours which was published after this paper was first submitted (p. 26).

On page 28 we added reference to a new December 2008 study that is relevant to our discussion of biomonitoring and its potential impacts on breastfeeding behavior:

“A recent survey of breastfeeding women suggests that learning about the presence of chemicals in their breast milk may lead them to wean earlier than intended [64], although the survey for this study was hypothetical and did not actually measure whether in fact reporting monitoring results actually changed the duration of breastfeeding.”

Finally, we changed one of the EWG studies we discussed on page 18 taking out the umbilical cord study and instead discussing a recent study examining chemical exposures from consumer products in teenage girls. The blood cord study did not have an opportunity for individual report-back to respondents since this monitoring was done on stored samples. The new text reads:

“The third study examined the presence of chemicals commonly used in cosmetics and body care products in teenaged girls. The study detected 16 chemicals from four chemical families - phthalates, triclosan, parabens, and musks - in blood and urine samples from 20 participants aged 14-19. Many of these chemicals are linked to potential health effects including cancer and hormone disruption [53].

We hope that these revisions address the reviewers’ and editors’ comments. If you have questions regarding our resubmission, please do not hesitate to contact me.

Very Truly Yours,

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