

Reviewer's report

Title: 'Toxic Ignorance' and the Right-to-Know: Assessing Strategies for Biomonitoring Results Communication in a Survey of Scientists and Study Participants

Version: 1 **Date:** 11 December 2008

Reviewer: Karel Van Damme

Reviewer's report:

This paper is presented as a scientific paper, and can be criticised as such. It is much closer to an opinion paper. This paper seems to illustrate – once more - that the traditional structure of a scientific paper does not always fit for 'ethics' papers. Editors should accept this. This makes it difficult to give a clear structure to the comment on this paper. I do hope that the comments below are nevertheless interesting to the authors and the editor. They all concern suggestion for discretionary revisions, with one exception: 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.

Minor essential revisions:

The paper has the merit of encouraging the debate on some major aspects of the communication of results of bio-monitoring research practices, also starting from some real life experience. This encouragement is needed, and it should therefore be published.

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.

One preliminary comment on the definition of the subject of the paper: 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.

The paper refers de facto (my suggestion is to say it explicitly) to a USA context. Within the EU for instance, the question 'how' communication should be done is always an issue. But in contrast with the USA, EU citizens have the undeniable right to have access to their own results. This right is guaranteed by the so called

EU privacy-Directive 95/46/EC (European Law).

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.

It seems that the authors rather preferred the enumeration of some contradictory considerations (issuing from their questioning, references and own comments), sometimes without even noticing their contradictory nature, and surely leaving the in depth analysis of that contradictory nature aside.

An example:

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.

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. Fore 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.

Another example:

At several occasions the involvement of the community is addressed. E.g. page17. 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 raising the question, even without necessarily providing elements to the answer.

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.

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.

Discretionary revisions:

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

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.

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.

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.

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

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

'I declare that I have no competing interests'