Author's response to reviews

Title: Re-focusing the ethical discourse on personalized medicine. A qualitative interview study with stakeholders in the German healthcare system

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Author's response to reviews: see over
Revision of MS: 1210987644908852 – Re-Focusing the Ethical Discourse on Individualized Medicine: A Qualitative Interview Study with Stakeholders in the German Healthcare System

To whom it may concern,

On behalf of the authors, I am enclosing a cover letter regarding our revised manuscript entitled “Re-Focusing the Ethical Discourse on Individualized Medicine. A Qualitative Interview Study with Stakeholders in the German Healthcare System” (MS: 1210987644908852). Please find below a point by point response (we refer to the revised version when citing our manuscript).

Editorial Requests:
Our study was exempt from formal ethical approval due to German regulations, which we refer to in the revised manuscript (p. 6).

An authors’ contributions section is now included (p. 18).

The revised manuscript conforms to the word template provided at http://www.biomedcentral.com/authors/medicine_journals.

Reviewer: 1 (Leonard Fleck):
Comments to the Author
First of all, it is surprising that reviewer 1 states that we did not “present something novel, interesting or important”, while reviewer 2 sees no need for any essential revisions, solely suggests some discretionary revisions, evaluates the paper as an “article of importance in its field” and states that “this is a first-rate paper and I definitely recommend publication”.

This might result from some misunderstandings. In fact, our study is a descriptive sociological inquiry followed up by some (normative) critical commentary. This seems to be an appropriate as well as adequate and plausible approach within biomedical ethics (according to, for instance, Weaver & Trevino 1994, Hope 1999, Sugarman & Sulmasy 2001, Borry et al. 2004, Holm & Jonas 2004, Solomon 2005, Leget et al. 2009).

Furthermore, the reviewer seems to conflate quantitative and qualitative empirical research: qualitative studies – like ours – are not representative (which we state, for instance, in the limitations section), but rather used to generate hypotheses (which we also state in the limitations section). Moreover, a sample of 17 individuals is usually considered to be sufficiently big within qualitative research. The usual size of a qualitative sample lies between
10 and 15 individuals. Furthermore, “saturation” is a well-known term in qualitative research: it does not mean “we got all the information we wanted”, but rather “we got all the information we could gather” (cf. reference [12] Given 2008: 697-8). As a consequence, we were surprised (and at the same time not surprised) by the statement of the reviewer that he could „think of other issues that were not identified“. In the (qualitative) empirical part of our paper, it is of no interest what we can think of, but rather what leading representatives (p. 6) of stakeholder groups in the German healthcare system can (and cannot). When analyzing the results, it is, in fact, interesting what these individuals do and do not think of, especially because they are leading representatives who do structure the discourse on PM and may influence the further development of PM by political or policy decisions. This is exactly what we present and discuss in the article (pp. 12-16).

As we explain in the background section (pp. 4-5), the goal was not to simply gather some beliefs, but rather “to understand how the ethical discourse on PM is conducted, i.e. on what – empirical and normative – assumptions ethical arguments are based regarding PM’s current and future developments”. One of the most interesting results is that the debate does not refer to judgments that the reviewer “would [have] reached (or any other thoughtful person would easily reach and endorse)”, but rather by – amongst others – politically motivated judgments. Against this background, it first seems important to present “bizarre comments” as well as “rumor-mongering”, especially as these statements were made by leading representatives who do shape the discourse on PM in Germany and influence political decisions (and we do discuss these statements; cf. discussion section). Second, this situation obviously makes it necessary to point to thoughtful judgments and analytical development in the context of PM, especially “in a respectable academic journal” focused on ethics: these judgments, in fact, could be reached easily by thoughtful individuals – they simply are not when it comes to the discussion of PM. And this seems to be an important result of our study (cf. review 2).

Finally, we do exemplarily discuss ethical issues that were not mentioned by the interviewees (cf. discussion section). However, a complete analytic explication and critical assessment of the ethical issues emerging in the field of PM would have made a different article. We do not present any argument stating that oncology „is the most active area of IM now and in the foreseeable future“. We solely present statements by our respondents and point to the fact that there exist other areas of PM which were not mentioned in the interviews (cf. discussion section).

Reviewer: 2 (Leslie P Francis):
We deleted the misplaced “the”s at the beginning of the article.

Regarding the “minor discretionary suggestions”:
As “personalized medicine” is the more common term in English-speaking countries, we substituted “individualized medicine (IM)” for “personalized medicine (PM)” in the whole text.

In our view, the debate on a potential discriminatory impact resulting from personalized therapy seems to center around possible consequences for certain individuals arising from
diagnostic test results. In this context, we already mentioned the potential for discrimination of certain individuals (p. 4).

Regarding the possibility of selection bias, we explicitly mention two possible causes: first, the respondents’ specific working fields and personal interests (p. 13 & 15). Second, the sampling differences in comparison to another German study (p. 14). Furthermore, our sample did include statisticians (subsumed under the category “health economists”). We added an accordant note (p. 5).

Our study shows that no ethical issues were mentioned in the interviews that arise exclusively (p. 14). Neither do we see “unique problems emerging”. Against this background, we added a sentence stating that relevant ethical concerns have to be approached by referring to standard bioethics debates and applying accordant approaches (p. 17).

We do not conflate “ethical issues in the rhetoric of IM with ethical issues in IM”. We solely speak in terms of reviewer 2’s point (b). Accordingly, we tried to make this point clearer (p. 15). Furthermore, we only use medical terms like “good responder” or “non-responder” while setting aside terms like “poor responder”.

We added a sentence in the limitations section stating what further research could address (p. 18).

On behalf of the authors, I would like to thank you again for reviewing and considering our article. I am looking forward to your decision.

Yours sincerely,

Sebastian Schleidgen