

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Public views on the donation and use of human biological samples in biomedical research – a mixed methods study
AUTHORS	Lewis, Celine; Clotworthy, Margaret; Hilton, Shona; Magee, Caroline; Robertson, Mark; Stubbins, Lesley; Corfield, Jule

VERSION 1 - REVIEW

REVIEWER	Wendy Lipworth NH&MRC Postdoctoral Research Fellow Australian Institute of Health Innovation, University of New South Wales Australia I have no competing interests.
REVIEW RETURNED	05-May-2013

THE STUDY	<p>1. It is true that most existing research is not specifically focused on attitudes to donating different tissue types. But such information is embedded in at least some of the existing research and I think that there should be at least some effort to refer to what is already known.</p> <p>2. I am not a quantitative researcher, so I cannot comment on the survey design or analysis.</p> <p>3. It seems a bit odd to refer to an unpublished manuscript for further detail on the study methods.</p>
RESULTS & CONCLUSIONS	<p>1. You say, on page 17, that: “Another striking finding was the apparent discrepancy between people who saw biosample donation as important (87%) and those who wanted to be asked to donate (75%).” Please explain why you see this as a discrepancy. Willingness to participate and wanting to be asked seem to me to be completely compatible. People often want to be asked simply out of respect—not because they are afraid and reluctant.</p> <p>2. One of your major conclusions is that there is a need for greater transparency and discussion in order to increase support for biobanking research. But levels of support are already very high. Is there a contradiction here? How do you explain this? Is the issue that certain subgroups are under-represented and that certain kinds of tissue are infrequently donated? In this case, isn't the issue the need for much more focused communication?</p> <p>Minor corrections</p> <p>1. Page 3 line 42: Should be “acceptable TO donate”</p> <p>2. On Page 4 you say that: “Biobanks are important custodians of HBS collections, usually with access to the donors’ phenotypic and clinical data”. It is probably worth specifying that this information is</p>

	almost always de-identified. 3. P11 line 30: Should be “could RESULT from”
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REVIEWER	Maria Olejaz Ph D Student Centre for Medical Science and Technology Studies, Department of Public Health University of Copenhagen No competing interests
REVIEW RETURNED	15-May-2013

THE STUDY	<p>I found the use of mixed methods very relevant but the authors should consider three points. Firstly, it would be good with a brief explanation as to why focus groups and not in-depth individual interviews were chosen. Both methods can be very relevant tools but for different purposes. The motivation for the authors' choice of qualitative method could thus be clearer spelt out in the article. My second point in regards to methods is that is it unclear how the findings from the focus groups have fed into the development of the survey. A brief description of this work could be helpful for the reader.</p> <p>A third comment relates to the methods as well as to the limitations of the study. In both the focus groups and the survey an information sheet about the subject matter (donating biomedical samples for research) was introduced to the informants before or during the study. Why this was done? Please explain. Moreover, the authors need to explain the potential implications of this information sheet for their findings. It could be argued that introducing such an information sheet frames the subject matter that you want to explore in a certain way for the informants, thereby influencing the sort of answers that you get from the informants. This is not just a methodological issue but also an important limitation to the study as it has implications for the representativeness of the findings. The attitudes that the study has uncovered are as such not necessarily the attitudes of the general public but the attitudes of people from the general public, who have received specific information about the subject matter they are being asked about. This should be discussed by the authors in the article.</p>
RESULTS & CONCLUSIONS	I find the results very well represented and credible especially when the authors link them directly to the empirical data. However the conclusion could be improved. In the conclusion public education is proposed as a possible solution to the concerns that the study has uncovered. It would benefit the conclusion if the authors included issues of trust and transparency in the conclusion, as they are very importantly brought up in the discussion of the article. Reducing the public concerns on trust and transparency to an issue of giving more information is not adequate. Therefore including public trust as a subject in its own right in the conclusion would be fruitful for the article as a whole and would better reflect the actual findings of the study.
GENERAL COMMENTS	This is a relevant and timely study. Asking questions about different types of bodily material and different potential uses seems very relevant as it seems to matter to the public and to be reflected in their donation choices. Linking attitudes to bodily donation to issues of trust as was done in the discussion also seems fitting a long with the aim of balancing public concerns and public governance.

VERSION 1 – AUTHOR RESPONSE

Reviewer: Wendy Lipworth
NH&MRC Postdoctoral Research Fellow
Australian Institute of Health Innovation, University of New South Wales Australia

I have no competing interests.

It is true that most existing research is not specifically focused on attitudes to donating different tissue types. But such information is embedded in at least some of the existing research and I think that there should be at least some effort to refer to what is already known.

We have added the following paragraph to provide more background information on what is known in this area:

Less well known are the public's views regarding the types of HBS acceptable to donate, under what circumstances and for what research purposes, although some research does exist in these areas. For example, research has shown the public are generally willing to donate diseased tissue or 'waste material' (such as cancerous tissue or placental tissue) for biomedical research, however, donation of eyes, brains, lungs and bone is far more contentious [Goodson 2004; Morrell 2011; Barr 2006]. Regarding access to tissues, research by publicly-funded academic researchers has been shown to cause few concerns, in comparison to research conducted by commercial entities [Haddow 2008; Budimir 2011; Lipworth 2009].

It seems a bit odd to refer to an unpublished manuscript for further detail on the study methods.

This 'unpublished manuscript' is currently also going through the review process with BMJ Open and is currently at the 'accepted with minor revisions' stage. We are hoping that the 2 papers will be published side by side in the same edition. We will update the reference as and when we know the outcome of the other paper (ideally we will just add a link here to the other paper).

You say, on page 17, that: "Another striking finding was the apparent discrepancy between people who saw biosample donation as important (87%) and those who wanted to be asked to donate (75%). " Please explain why you see this as a discrepancy. Willingness to participate and wanting to be asked seem to me to be completely compatible. People often want to be asked simply out of respect—not because they are afraid and reluctant.

We agree that this isn't necessarily a contradictory finding. We have therefore amended the sentence to read:

We identified that more people saw biosample donation as important (87%) than wanted to be asked to donate (75%).

One of your major conclusions is that there is a need for greater transparency and discussion in order to increase support for biobanking research. But levels of support are already very high. Is there a contradiction here? How do you explain this? Is the issue that certain subgroups are under-represented and that certain kinds of tissue are infrequently donated? In this case, isn't the issue the need for much more focused communication?

One of our 'key messages' is that "Concerns exist regarding the use of certain types of samples, the conditions under which they are used and data security; greater transparency and discussion of the safeguards that exist in research is likely to alleviate some of these concerns." We do not mean to suggest that greater transparency and discussion will increase support for biobanking, because, as

you say, support is already high. Nevertheless, people were still found to have concerns about certain issues even if they were not 'deal breakers' i.e. they do not preclude participation. We have, however, tried to make this point clearer in the manuscript, and also agree that we could emphasise the need for more focused communication to address the issues that certain subgroups are under-represented and certain tissue types infrequently donated. We have therefore amended the manuscript as follows: In the key message we have added the following:

More focused communication may also help address the issue that certain subgroups are under-represented and that certain kinds of tissue are infrequently donated.

In the conclusion we have amended the last few sentences to say:

Nevertheless, underlying concerns exist regarding the use of certain types of HBS, the conditions under which they are used and data security, although these issues did not necessarily preclude willingness to participate.

AND

More controlled forms of consent and focused communication for sensitive types of HBS may also positively impact public willingness to donate infrequently donated tissue types. More focused communication may also address the finding that certain sub-groups, such as particular minority ethnic groups, are less likely to donate.

Minor corrections

1. Page 3 line 42: Should be "acceptable TO donate"
2. On Page 4 you say that: "Biobanks are important custodians of HBS collections, usually with access to the donors' phenotypic and clinical data". It is probably worth specifying that this information is almost always de-identified.
3. P11 line 30: Should be "could RESULT from"

Thank you for pointing these out – we have made the corrections.

Reviewer: Maria Olejaz
Ph D Student
Centre for Medical Science and Technology Studies,
Department of Public Health
University of Copenhagen

No competing interests

I found the use of mixed methods very relevant but the authors should consider three points. Firstly, it would be good with a brief explanation as to why focus groups and not in-depth individual interviews were chosen. Both methods can be very relevant tools but for different purposes. The motivation for the authors' choice of qualitative method could thus be clearer spelt out in the article.

We have added the following sentences to explain why we used focus groups rather than in-depth interviews.

Focus groups were chosen as this method helps people explore and illuminate their views through debate within the group. They can also help facilitate the expression of ideas that might be left underdeveloped in an interview [Kitzinger 2006]. Focus groups have been used successfully to study the attitudes of the general public in relation to biobanking in previous research [Tutton 2007; Haddow 2010].

My second point in regards to methods is that is it unclear how the findings from the focus groups have fed into the development of the survey. A brief description of this work could be helpful for the

reader.

We have added the following to address this point:

Key themes that were discussed or emerged from focus group discussions were reframed as survey questions; in a number of cases answer options in the survey were informed by focus group discussions (e.g. the different types of residual HBS participants were presented with were raised by focus group participants).

A third comment relates to the methods as well as to the limitations of the study. In both the focus groups and the survey an information sheet about the subject matter (donating biomedical samples for research) was introduced to the informants before or during the study. Why this was done? Please explain. Moreover, the authors need to explain the potential implications of this information sheet for their findings. It could be argued that introducing such an information sheet frames the subject matter that you want to explore in a certain way for the informants, thereby influencing the sort of answers that you get from the informants. This is not just a methodological issue but also an important limitation to the study as it has implications for the representativeness of the findings. The attitudes that the study has uncovered are as such not necessarily the attitudes of the general public but the attitudes of people from the general public, who have received specific information about the subject matter they are being asked about. This should be discussed by the authors in the article.

The focus group participants were given an information sheet prior to taking part in the focus group discussion. Survey participants were not given this information sheet and were only given information necessary to be able to answer the survey questions (a reduced version of the information sheet). For that reason, focus group participants were far more informed about donating biosamples for research than survey participants were (they also had the opportunity to ask questions at the beginning of the session which survey participants obviously could not do). We did also try to ensure the information sheet was not biased in any way towards donating – we tried to do this by checking the objectivity of the information with Sense about Science (a communication charity) and a number of patient members of Genetic Alliance UK. We do however think this is an important point the reviewer raises, and are aware that any information may influence the answers survey participants give. We have therefore addressed these points as follows:

In the methods section (focus groups) we have added the following:

Prior to the day, focus group participants were given an information sheet about the use of biosamples in research in order that they had some background knowledge about the subject matter and to get them thinking about the key issues (Appendix I).

In the methods section (survey) we have added the following:

Survey participants were not given the background information sheet about the use of biosamples in research which was given to all focus group participants. This was so that the survey responses represented the attitudes of the general public as far as possible. They were, however, given information during the survey to enable them to make informed decisions when answering the survey questions.

In the limitations we have added the following:

We also provided focus group participants with a background information sheet so that they had some knowledge about the subject matter before the discussion took place, and as such were likely to be more well informed than the general public. Survey participants were not given this information sheet and were only given selective background information that it was felt (by the authors) was necessary

to enable them to make informed decision when answering the questions. This in itself, however, may have impacted the representativeness of the findings as they may have responded differently if no background information had been provided.

I find the results very well represented and credible especially when the authors link them directly to the empirical data. However the conclusion could be improved. In the conclusion public education is proposed as a possible solution to the concerns that the study has uncovered. It would benefit the conclusion if the authors included issues of trust and transparency in the conclusion, as they are very importantly brought up in the discussion of the article. Reducing the public concerns on trust and transparency to an issue of giving more information is not adequate. Therefore including public trust as a subject in its own right in the conclusion would be fruitful for the article as a whole and would better reflect the actual findings of the study.

We have expanded the conclusion to address the issues raised by the reviewer. The final section of the conclusion now reads:

More controlled forms of consent and focused communication for sensitive types of HBS and donation incentives may also positively impact public willingness to donate infrequently donated tissue types. More focused communication may also address the finding that certain sub-groups, such as particular minority ethnic groups, are less likely to donate. Finally, greater transparency in the biomedical research process and the fostering of trust in those organisations involved throughout that process is vital to ensure the process of donating tissue to biobanks is satisfactory to all parties involved. These suggestions should be considered by the research community and policy makers.

This is a relevant and timely study. Asking questions about different types of bodily material and different potential uses seems very relevant as it seems to matter to the public and to be reflected in their donation choices. Linking attitudes to bodily donation to issues of trust as was done in the discussion also seems fitting a long with the aim of balancing public concerns and public governance.

VERSION 2 – REVIEW

REVIEWER	Maria Olejaz Ph D Student Centre for Medical Science and Technology Studies Section for Health Services Research Department of Public Health University of Copenhagen Denmark
REVIEW RETURNED	25-Jun-2013

- The reviewer completed the checklist but made no further comments.