

Why governance? A challenge to good governance of biobanks

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Abstract In this commentary on Karla Stroud and Kieran O’Doherty’s ‘Ethically Sustainable Governance in the Biobanking of Eggs and Embryos for Research’ (2015) I call into question the need for good governance to overcome the challenges facing biobanking of eggs and embryos. I argue that the principles of good governance for biobanking that Stroud and O’Doherty outline come up short in providing concrete normative guidance to resolve the challenges associated with a biobank for eggs and embryos.

Keywords Biobank · Eggs · Embryos · Governance · Health research · Informed consent

1 Introduction

In their paper, ‘Ethically Sustainable Governance in the Biobanking of Eggs and Embryos for Research’, Stroud and O’Doherty (2015) discuss the challenges that would arise in relation to the (hypothetical) establishment of a biobank for eggs and embryos in Canada. Taken as a given is the view that a biobank for eggs and embryos requires good governance (Caulfield et al. 2008), and that good governance ought to adhere to three principles: (1) trustworthiness, (2) collectivity, and (3) adaptivity (Stroud and O’Doherty 2015; O’Doherty et al. 2011). The central ambition of the paper is to articulate how these principles can be put into practice for biobanks for eggs and embryos.

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Stroud and O'Doherty do a fine job outlining the key challenges for biobanking of eggs and embryos. These challenges come from two main sources. The first is the nature of the biobank itself and the materials it houses. Biobanks for research, generally, pose challenges about privacy, management of findings from research, ownership, and informed consent. As Stroud and O'Doherty illustrate, these challenges may be more acute in the case of eggs and embryos because they are created from the gametes of (at least) two donors. The second source of challenges is the current Canadian regulatory landscape. Stroud and O'Doherty provide an extensive overview of existing Canadian regulations concerning eggs and embryos for research. Importantly, the authors' discussion highlights the barriers that would need to be overcome before any of the first set of challenges arising from the nature of the biobank—particularly informed consent—can be met.

The authors locate the most promising solution to overcoming the challenges facing biobanks for eggs and embryos in good governance. Left unanswered, however, are basic questions about the nature of governance, what alternatives there are to governance, what makes governance good, and how principles of good governance can be put into action. In what follows, I will try to clarify these questions. I will argue that, while Stroud and O'Doherty outline indisputable virtues that good governance of biobanks for eggs and embryos should possess, their account lacks concrete normative guidance to answer the important challenges that such biobanks face. This leaves unresolved why a governance structure ought to be adopted and how such a structure should arrive at decisions it may be called on to make. I end by pointing to possible ways to remedy this lacuna.

2 Concerns about biobanks (for eggs and embryos)

Biobanks serve as repositories for human biospecimens. Such specimens include cells, tissues and organs, gametes (sperm and eggs), and embryos (Cambon-Thomsen 2004). Given the kind of materials that they house, biobanks are important resources for scientific research. But research involving materials derived from biobanks raises a number of important ethical concerns that have been articulated in the literature (Budimir et al. 2011). These concerns stem both from the nature of the biospecimens involved and the biobank itself and include:

- (1) *Ownership*: who owns the materials donated to the biobank— the donors from which they are derived, the biobank that houses those materials, or the researchers (or the researchers' institution) conducting research?
- (2) *Privacy*: given that biospecimens may reveal important personal health or genetic material, how should the privacy of donors be protected?
- (3) *Management of findings*: what should be done if there are important health-related findings from research involving biospecimens?
- (4) *Informed consent*: given that biobanks are long-lived and may house specimens for research that will take place well in the future, how can the donors give fully informed consent for research that may not even be conceived yet?

The focus of Stroud and O’Doherty’s paper is biobanks for eggs and embryos. Currently, no such biobanks exist in Canada. According to the authors, a biobank for eggs and embryos, if one were to be established, would face the same kinds of challenges that biobanks for other kinds of biospecimens do. But they also demonstrate that biobanks for eggs and embryos would face unique challenges, because of the particular materials that are involved. For example, they suggest that gamete donors may have particular concerns about privacy if they do not wish their families to know that they have used IVF to create an embryo. Additionally, the fact that embryos are created by at least two donors may complicate questions of ownership.

The authors focus their attention on the issue of informed consent and I will here follow suit. The central concern is that the nature of biobanks makes obtaining informed consent in compliance with the specific consent model required by Canadian legislation difficult. In particular, the longevity of biobanks means that human tissues may be stored for long periods of time and used for research at a much later date (Greely 2007). On the specific consent model, I can consent at a certain time (T1) for my biospecimen to be used for purposes x, y, and z at T2. In this case, given that I am informed about the possible purposes x, y, and z for which my biospecimen may be used at T2, I can give informed consent for what happens to it at T2. But the difficulty arises when consent is needed for research that may happen many years down the line (at T_n) and for purposes that may not yet be known.

3 ‘Good governance’ of biobanks for eggs and embryos

Stroud and O’Doherty claim that the best way to resolve the challenges associated with biobanks is through good governance. ‘Governance’, however, can be understood in a number of ways (Graham et al. 2003). The authors do not offer a definition, but I take them to propose governance as an alternative to obtaining specific consent by parties involved, in which others make decisions on their behalf. But they do not explain why refined views of consent (e.g., open consent, tiered consent, and dynamic consent) cannot be used to make the necessary decisions, nor why governance is a superior alternative.

To evaluate the authors’ proposal we must now ask: what is good governance? There are two ways of understanding it. The first is procedural: as a description of the way in which decision-making concerning the activities of the biobank should be made. On this view, good governance will identify who should be involved in these decisions, how decisions should be made, who is accountable for those decisions, and accountable to whom. I take the general principles that Stroud and O’Doherty articulate that should underlie ‘good’ (or, in their words, ‘ethically sustainable’ and later, ‘adaptive’) governance—of trustworthiness, collectivity, and adaptivity—to refer to this understanding of governance.

But if we return to some of the challenges that Stroud and O’Doherty contend are best addressed through good governance—privacy, ownership, management of findings, or informed consent—we might ask how decision-making by a governing

body that is trustworthy, collective, and adaptive will help to settle these issues. Consider, for example, informed consent. Suppose that donor A has donated her embryos to the biobank. Under the specific consent model, it is not possible for A to give informed consent for the use of her embryos in research at some future time (T_n) because it is not possible to conceive of all possible research purposes at T_n.

But it is not obvious how implementing governance that is trustworthy, collective, and adaptive will help to resolve this difficulty. Stroud and O'Doherty expand on trustworthiness by explaining that biobank governance is trustworthy only if it is representative, accountable, transparent, reflective, and sustainable. They say further that recognizing collectivity requires recognizing the right of biospecimen donors to share in the power over the resources and benefits from their specimens, and that in order for governance to be adaptive, it needs to be reflexive to changing conditions.

However, this framework requires far more detail before it can be put into practice. Suppose that an embryo donor comes to a biobank with her embryos. The director of the biobank tells her that there is a governance structure in place that is transparent, collective, and adaptive. How does this resolve the issue of informed consent? Perhaps the donor can consent to leaving the decision about what to do with her embryos to the biobank. That is, she can consent to a governing body doing the deliberation for her. But even so, it is not clear how informed the consent she can give to that will be. How will she know what kind of decisions will be made concerning her embryos? Even if the donor is told the decision will be adaptive, transparent, and collective, it is not obvious that her consent to have a governing body make such decisions for her would be any more informed than would be her consent to as yet unspecified future research, where she does her best to say what she would and would not want done with her embryos.

This brings us to the second way of understanding good governance: as a concrete set of guidelines that cover all contingencies. It seems that an answer to the problems that arise in biobanks—of privacy, ownership, management of findings, and informed consent—will call for such guidelines. Such guidelines may articulate, for example, how and what kind of research should be carried out and under what conditions, as well as how to guard against privacy breaches and the kind of information about donors that may be shared and under what conditions, what the conditions are for ownership of the biospecimens, and whether and how informed consent be obtained. If so, it is not obvious how the principles Stroud and O'Doherty identify—trustworthiness, collectivity, and adaptivity—would help create such guidelines. Nor is it obvious why one should appeal to a governance structure at all, rather than the principles by which such decisions will eventually be made.

4 Operationalizing good governance

The operationalization of the principles of good governance raises a final potential difficulty. If we accept that good governance will help to resolve the challenges that face biobanking of eggs and embryos, and if we accept that good governance should

be governance that is trustworthy, adaptive, and collective, the remaining question to be answered is how to operationalize that kind of governance. Stroud and O'Doherty emphasize the importance of acknowledging and respecting the plurality of values and beliefs that people hold with respect to the kinds of decisions and practices that may be related to biobanks. They identify potential key stakeholders, who could include donors, religious groups, scientists, patients, illness groups, and the broader public. As the authors rightly note, these stakeholders will hold a plurality of—sometimes conflicting—positions and values related to the activities of the biobank. Taking into account this plurality of perspectives will be no easy task. Stroud and O'Doherty locate the most promising avenue to do so in what they refer to as 'deliberative public engagement' (Stroud and O'Doherty 2015: 19; O'Doherty and Burgess 2013).

This is a promising suggestion. However, the authors do not articulate what the end of such deliberation should be or how conflicts of opinion should be resolved. This gives reason to be skeptical that public deliberation will yield an outcome that is normatively useful. This is especially so on matters like the use of eggs and embryos for research, on which public opinion will vary dramatically and on which moral disagreement is likely.

To overcome this difficulty, one might draw on the rich body of philosophical literature that addresses which principles should guide public deliberation and how outcomes of such deliberation should be decided. This literature includes the work of John Rawls (1993), whose concept of overlapping consensus provides a theoretical framework to arrive at consensus in the presence of differing political opinions. Influential to this discussion also is the work of Joshua Cohen (1989), a student of Rawls, who maintains that public deliberation should aim at consensus, and disagreement settled by majority rule.

Practical guidance may also be found in other institutions that have successfully employed deliberative democratic procedures. Since biobanking and regulations concerning eggs and embryos is relatively new territory, existing biobanks cannot simply be copied. But one might seek guidance from analogous institutions for operationalizing good governance. To that end, the literature on the British Columbia Citizens' Assembly on electoral reform (Lang 2007; Warren and Pearse 2008), for example, may serve as a model for incorporating public input into the governance structure, and so to move from principles of good governance to actual institutional structures and rules.

5 Conclusion

While Stroud and O'Doherty identify important challenges for a biobank for eggs and embryos, the principles of good governance that they present to address them cover at once too much and too little: too much, in that they provide highly general principles that are hard to dispute; too little, in that they are so general so as not to provide any concrete normative guidance. The difficulty lies in the fact that such principles articulate virtues that a governance structure should have rather than ethical principles that should guide it. Insofar as the aim of good governance is to

arrive at conclusions about what to do in concrete situations that are ethically defensible—conclusions that, if challenged, can be backed by reason—recommendations for good governance will require an appeal to principles of ethics rather than virtues of the biobank.

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