Human Embryos and Eggs:

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Abstract: 197 words

Genetic relatedness poses significant challenges to traditional practices of medical ethics as concerns the biobanking of human biological samples. In this paper, we first outline the ethical challenges to informed consent and confidentiality as these apply to human biobanks, irrespective of the type of tissue being stored. We argue that the *shared* nature of genetic information has clear implications for informed consent, and the *identifying* nature of biological samples and information has clear implications for promises of confidentiality. Next, with regard to the special case of biobanking human embryos and eggs, we consider issues arising from: first, the *type* of tissues being stored; second, the *use* to which these tissues are put; and third, how this plays out given the *shared* and *identifying* nature of these tissues. Specifically, we examine the differences between human bodily tissues and human reproductive tissues focusing on the assumed potential of the reproductive tissues and on the possible greater emotional attachment to these tissues because of their real and imagined kinship. For some donors there may be a sense of family connection with embryos and eggs they once thought of as "children-in-waiting". Finally, we conclude by considering the implications for ethical practice.

Key Words: *5 to 20 key words or short phrases in alphabetical order*

Biobanking; long-term storage; embryos; eggs; oocytes; cryopreservation; consent; confidentiality; reproduction; research; genetic research; genetic relatedness; shared information; identifying information

Introduction

Published estimates confirm that there are millions of frozen human embryos in fertility clinics and off-site storage facilities in North America.[1] This is the result of practice patterns at fertility clinics and the absence of legislation on storage limits. While there are no comparable published estimates on the number of frozen human embryos in other jurisdictions, they very likely also number in the millions given similar practice patterns.[2] One important difference, however, is that in some of these others jurisdictions, including the United Kingdom, Australia, and New Zealand, there are legislated storage limits. These limits curb the increase. By comparison, we don't have many estimates on the number of human eggs currently in storage.[3] At present, most of the human eggs in storage are retained with the intention that they will be used for reproductive purposes. Some of these eggs are for third-party reproduction, as when eggs have been sold by individual women to brokers who market these eggs, and some of these eggs are for the provider's own reproductive use. In this second category there are eggs stored by women undergoing treatments that could affect their fertility, as well as eggs stored by women who anticipate fertility decline due to natural ageing (so-called fertility preservation for medical or social reasons) (Baylis 2015; Petropanagos et al. 2015). Whatever the number of human eggs currently in storage, this number will likely increase exponentially as more women become aware of the option of social egg freezing. This practice is now widely promoted by for-profit businesses, and enthusiastically supported by major technology companies (such as Facebook, Apple and Intel) that have added this to their benefit package. It follows that in the coming years, stored human eggs might also number in the millions.

Of the human embryos originally stored for the provider's own reproductive use, many are no longer wanted for this purpose. In the next five to ten years, this may also be true for eggs currently stored for the future reproduction by the egg provider. In principle, unused embryos and eggs can be donated for third-party reproduction, training to improve assisted human reproduction or to provide instruction in assisted human reproduction, or research. When the decision is to donate to research, there is an important change in the ontological status of the stored tissues (that may or may not be accompanied by a change in location), as the reproductive material moves from the category of long-term storage for possible future reproductive use to the category of biobanking for possible future research use. This change in ontological status raises a number of concerns that must be addressed for the biobanking of human embryos and eggs to be an ethical practice.

In this paper, we first outline the ethical challenges to informed consent and confidentiality as these apply to human biobanks, irrespective of the type of tissue being stored. We argue that the *shared* nature of genetic information has clear implications for informed consent, and the *identifying* nature of biological samples and information has clear implications for promises

[1] In 2003, Hoffman and colleagues estimated there were approximately 400,000 embryos in storage in the United States (1068). That same year, Baylis and colleagues estimated the Canadian total at 15,615 (2003: 1026). The most recent estimate for the United States is 1.4 million human embryos in storage (see, Lomax and Trounson 2013). While this estimate is flawed (see Snow, Cattapan and Baylis 2015), there is no doubt that the total is likely well over a million. There is no more recent estimate for Canada.

[2] The European Society of Human Reproduction and Embryology reports an average of 1.5 million ART cycles per year worldwide. (See https://www.eshre.eu/guidelines-and-legal/art-fact-sheet.aspx) Each of these cycles likely results in one or more embryos in storage.

[3] The HFEA in the United Kingdom reports that as at December 2012, there were approximately 18,000 eggs in storage for own use. The usual limit on egg freezing is 10 years. (See www.hfea.gov.uk/46.html)

of confidentiality. Next, with regard to the special case of biobanking human embryos and eggs, we consider issues arising from: first, the *type* of tissues being stored; second, the *use* to which these tissues are put; and third, how this plays out given the *shared* and *identifying* nature of these tissues. Specifically, we examine the differences between human bodily tissues and human reproductive tissues focusing on the assumed potential of the reproductive tissues and on the possible greater emotional attachment to these tissues because of their real and imagined kinship. For some donors there may be a sense of family connection with embryos and eggs they once thought of as "children-in-waiting".[4] Finally, we conclude by considering the implications for ethical practice.

Human biobanks

There is, as yet, no single authoritative definition of human biobanks (Boyer et al. 2012; Shaw et al. 2014). Common features include the collection, storage and distribution of specimens and data. These collections might be for diagnostic, therapeutic or research purposes and the storage may be in commercial, university-based, government-funded, or non-profit facilities. Recently, the Organisation for Economic Co-operation and Development (OECD) has stipulated that biobanks are "structured resources that can be used for the purpose of genetic research and which include: a) human biological materials and/or information generated from the analysis of the same; and b) extensive associated information" (2009: 22).

For the purpose of our analysis, we offer the following definition and brief description. Human biobanks are collections of human biological samples (such as, saliva, blood, urine, nail clippings, tumours) and information (about such things as health, family history, lifestyle, work, and memory) stored for research use; this may be health-related research or research involving heritage and ancestry tracing. Until the 1990s these collections – sometimes referred to as biorepositories – were small by contemporary standards (De Souza and Greenspan 2013). The biological samples and information were mostly obtained from patients undergoing testing or treatment who would donate their samples to a known researcher (or research institute), for a known project, or a known research objective in which they may have had a particular interest. A classic example of this would be the 23 extended families (329 participating relatives) with 146 cases of breast cancer who contributed samples that would eventually led to the discovery of the BRCA1 locus, and the identification of the inherited BRCA1 or BRCA2 mutations (indicators for breast and ovarian cancer) (Hall et al. 1990).

This pattern of practice changed quite dramatically when genome-wide scanning became possible and cost-effective, and when the sharing of data from genome-wide scans became technologically feasible. These changes facilitated the use of existing data which diminished the need for researchers to create their own collections. Researchers wishing to study a particular disease could simply request access to existing biological samples and information. In turn, this change created incentives for the mass collection and storage of samples and information by governments, charities focused on disease research, and for-profit companies. Thus, data collected from genome-wide scans for one purpose could be widely available to researchers and research organizations for other purposes.

[4] To be clear, this is a claim about emotional attachment, not a claim about moral status.

Human biobanks are research repositories or libraries that store biological samples or information, or both, from both patients and populations for future research. They are not themselves discrete research projects. These samples are often collected, stored and managed by national research organizations (such as, the US National Cancer Institute), national charities (such as, UK biobank), and private companies (such as, 23andMe and Knome Inc). Because informed consent to biobanking is not for a specific research project, generally donors will be asked to provide some kind of a 'broad' consent "for an unspecified range of future research subject to a few content and/or process restrictions" (Grady 2015: 35). This is not always the case, however. For example, the UK biobank uses a model of broad consent coupled with on-going governance by the Ethics and Governance Council (UKB EGF 2007). There are no *a priori* restrictions on the purpose of research, but these can be imposed, as appropriate, by the Ethics and Governance Council which must consider participants' wishes over-time and in light of future developments.[5] 23andMe, a direct-to-consumer genetic testing company, has a research advisory committee to oversee collaborative research involving access to aggregated data, but has promised that individual level data will only be shared with the express consent of the customer.

An important consequence of these myriad changes from biorepositories to biobanks is that whereas in the past those contributing biological samples and information to a biobank were often patients with some general understanding of the likely future research use of their samples and information, this is no longer the case. Previously, donors would have known that they were contributing their samples and information to research that aimed to discover more about a specific disease and ultimately to develop methods for prevention, diagnosis and treatment. With the current norm of broad consent to biobanking, donors may know very little about what research their samples and information will be used for, and the possibilities are endless – arguably, anything broadly conceived as 'in the public interest'.

In our estimation, collections of human embryos and eggs in storage for future research use, though not necessarily stored and managed centrally, qualify as human biobanks (even if they are not so named).

Ethical challenges with human biobanks

There are a number of ethical challenges with human biobanks many of which arise from the *shared* and *identifying* nature of the biological samples and accompanying information. These challenges call into question traditional ethical practices of informed consent and confidentiality.[6]

That which is shared: Informed consent

Genetic information is *shared* in the sense that, unlike other medical information, it is not only about one individual (Widdows 2013: 36ff). Genetic information is about related persons, kinship and ethnic groups, as well as wider groups; the closer the relationship, the

[5] UK Biobank had adopted a 'trust' model that goes beyond simple broad consent. The Ethics and Governance Council has an on-going remit to (i) ensure that UK Biobank abides by the Ethics and Governance Framework and (ii) monitor UK Biobank's duties to participants, its relationship with users of the resource, the principles and mechanisms of access, as well as wider duties to society (UKB EGF 2007).

[6] That genetic samples and information are shared and identifying is standard in genetic ethics, for overview of these arguments. See, Widdows (2007 and 2009).

more shared the information. The shared nature of the genetic information is evident in many contexts from family genetic testing, to population research, to biobanking.

Consider, for example, genetic testing for BRCA1 or BRCA2. If an individual tests positive, this information is relevant to, and can have an impact on, family members in a number of different ways. Firstly, if a woman tests positive for BRCA1 or BRCA2, then her mother or father will also be positive, and her children may be positive. Accordingly, it is possible to reveal the genetic status (or possible genetic status) of family members who have not chosen to be tested. Second, in response to the genetic testing of one family member, others may wish to be tested. Alternatively, depending upon the genetic condition, family members may be upset at having genetic information foisted upon them. Thirdly, depending upon the genetic condition, sexual partners of those who have had genetic testing may want access to information they deem relevant to their reproductive decision-making.

The shared nature of genetic information is also evident within broader groups. For example, there is the use of genetic testing by aboriginal groups as a tool for determining tribal enrolment or for investigating ancestral relations among indigenous peoples. In addition, as human biobanks are future-orientated and long-lived, biological samples and information stored in biobanks can have important consequences for those who do not yet exist – future offspring as well as future generations. There is no deep appreciation of this all important fact with current approaches to informed consent for biobanking (Cordell and Widdows 2010; Widdows and Cordell 2011).

Because the biological samples and information stored and managed in human biobanks are intended for future research use, traditional research ethics practices including practices of informed consent to research participation are widely used. The basic elements of informed consent are competence, disclosure, understanding, voluntariness and authorization (Faden and Beauchamp 1986). The disclosure element for informed consent to research requires giving information to prospective research participants about a number of facets of the proposed research. Here, we focus on those facets that readily carry over to biobanking, including: the purpose(s); the foreseeable potential harms; the right to withdraw; and, as applicable, the anticipated commercialization of research results (at which time research participants are invariably informed that they will not share in the profits). These disclosure requirements, already inadequate in the genetic era as a safeguard of ethical research, are especially problematic in the context of biobanking where broad consent is widely used (Bullock and Widdows 2011).

(a) Purpose(s)

As noted above, informed consent to contribute biological samples and information to a biobank serves as *de facto* informed consent to multiple, future discrete genetic research projects with potentially different purposes, in potentially different areas of research. The absence of specific information about the purpose(s) of unknown future genetic research raises discrete ethical issues for two kinds of prospective donors: those who regard scientific progress as a good in itself and want to participate in genetic research *irrespective* of the details; and those who have moral or other reasons for wanting to support some, but not all, future genetic research.

Prospective biobank donors willing to consent to the general purpose of advancing scientific research should be aware of the ways in which scientific progress is not a simple good, but

often comes with costs to self, to family, or to society. A potential future harm of genetic research is stigma and discrimination, which if brought to the attention of prospective biobank donors might have them reconsider the assumption that scientific progress is always for the good.

Other prospective biobank donors may have a genuine interest in (and need for) details about the purpose(s) of research involving the use of their biological samples and information. Consider, for example, genetic research that aims to develop a treatment for a specific congenital disorder as compared with genetic research that aims to develop a non-invasive prenatal test for that same congenital disorder. Individuals afflicted with the disorder may want to contribute to one, but not the other, of these two research objectives. Similarly, consider genetic research that aims to develop a stem cell therapy as compared with genetic research that aims to develop a new abortifacient. Again, it is easy to imagine that some individuals may want to contribute to one but not the other of these two research objectives. With consent to biobanking, donors may or may not be able to direct (or limit) the use of their biological samples and information to research consistent with goals they support/endorse as when information about the specific purpose(s) of the research is not available at the time of consent and there is not the option of consent to discrete categories of research.

(b) Potential harms

Generally, biobank donors can be informed of the general potential harms of participating in a biobank, but not the specific potential harms of particular research projects. This is because the specific research projects for which donated biological samples and information will be used may not be known at the time that consent to biobanking is solicited (though classes or categories of research may be known).

By and large, the potential harms of biobanking – rarely evident, or imminent, or even predictable, at the time that broad consent to biobanking is requested – derive from the potential harmful consequences of future genetic research for biobanking donors, related persons, communities, and the wider public. Potential harms to donors or related persons include unwanted identification, unsolicited information about genetic susceptibly and diseases, and the risk of stigma and discrimination. A recent example of harm in this last category is harm to persons with Down syndrome and their families resulting from the development of early non-invasive prenatal testing for Down syndrome (Kaposy 2013). More generally, potential harm to communities, include the harm of exploitation, as when materials and information donated to a biobank contribute to the development of preventive, diagnostic or treatment interventions that are not affordable or accessible. A good example of this is the research resulting in a patent for the Canavan gene[7]as well as carrier and prenatal testing using that gene (Marchant 2005: 161). Once the patent was granted, a licensing payment of US$12.50 was required for each test. This fee was above the cost that had previously allowed the Canavan Foundation to offer a free testing programme. Meanwhile, the Canavan Foundation (among others) had been instrumental in recruiting sufferers of the disease and

[7] Canavan disease is “an incurable recessive genetic disease that results in degeneration of the brain of children born with the condition followed by inevitable death usually between the ages of ten and fifteen” (Marchant 2005: 161). The disease is found amongst Ashkenazi Jews and approximately one in 6400 children are born with it (Marshall 2000).

persuading them to provide both samples and seed funding for the research that lead to the patent.

These harms – unwanted identification, unsolicited information about genetic susceptibly and diseases, potential stigma and discrimination, and the harms of exploitation – are not inconsequential, and yet they are not routinely disclosed in informed consent procedures. This may be because the harms are not threats to bodily integrity or physical risks and because some of the harms are communal rather than individual. Regardless, disclosure of these potential harms should be part of informed consent to biobanking.

(c) Right to withdraw

Depending upon how participation in a biobank is interpreted, it is not clear that withdrawal is always possible; this is especially true with large biobanking projects. For instance, UK Biobank grants donors the right to withdraw "at any time and without having to explain why and without penalty" (UKB EGF 2007: 6) and specifies three withdrawal options: 'no further contact', 'no further access', and 'no further use'. The option of 'no further use', however, does not amount to complete withdrawal: "UK Biobank would destroy their samples (although it may not be possible to trace and destroy all distributed anonymized sample remnants) and would only hold their information for archival audit purposes" (UKB EGF 2007: 9).[8] Accordingly, the safeguard of withdrawal does not function in biobanking as it usually does with much clinical research.

(d) Commercialization

Biobanks serve public and private, noncommerical and commercial interests. Prospective biobank donors can have access to information about funding when the biobank and related individual research projects are publicly funded. This is not the case, however, when the biological samples and information from public biobanks are used in commercially funded projects. UK Biobank, for example, is open to research from the commercial sector as well as the public sector. The tension between the altruism of donors in the public biobank and the potential exploitation of the banked samples and information for commercial purposes is well documented and of concern to at least some donors. As yet, this has not proven to be a significant difficulty but the potential for scandal remains (Widdows 2013: 140-144).

In the private sector, there is an added wrinkle. The individuals who contribute value to a private biobank are doing so at a cost to themselves insofar as their biological material and information is included in the bank following the purchase of direct-to-consumer genetic testing. For example, 23andMe charges US$199.00 for its genetic testing and as more and more individuals purchase the testing, the biobank becomes a more valuable repository. It has been said that the company aims to become the "Google of personalized health care" and this very much depends on having massive amounts of base level data (Murphy 2013). For now, the company is not paying for this data, the customer is.

That which is identifying: Confidentiality

[8] For a discussion of withdrawal in biobanking, see Holm (2011).

Biological samples and information are *identifying*, notwithstanding efforts at anonymization. Current practices of de-identification – where biological samples and information are coded or protected by a key or some other shield – can make identification within a discrete research project exceptionally unlikely, but no more than this. Simply put, no matter what efforts are made to remove identifying particulars, there will always be the possibility of identification because "DNA is itself uniquely identifiable" (McGuire 2008: 75). This means that the usual methods for protecting confidentiality are insufficient. Biological samples and information become readily identifiable when they are: compared to available information from other individuals or related persons; triangulated with other information; or used in new ways as techniques and technology improve (Widdows 2013: 43ff). Below we briefly explain each of these points.

First, biological samples and information can become identifying when they are compared with samples and information in a biobank. Indeed, database comparison for biological samples is conceptually similar to fingerprint comparison. As yet, however, this type of identification is relatively limited as there are few comparator genetic databases (especially when compared to fingerprint databases). However, human biobanks are proliferating in the medical and scientific communities and in the criminal and justice sectors. As well, and importantly, private human biobanks are expanding. One particular growth area is the direct-to-consumer genetic testing market led by companies such as 23andMe, deCODEme and Knome Inc. These companies provide genetic information to individuals who send in their biological samples for disease, heritage or ancestry testing. This results in vast stores of biological samples and information that can potentially be used as comparator databases.

Second, biological samples and information can become identifying via processes of triangulation. Triangulation, essentially means that individuals are identified by processes of elimination. Apparently anonymous DNA sequences are linked to publicly available qualifiers such as gender, age or postal code and individuals or small groups are thereby revealed. This happened dramatically in Iceland when its Supreme Court found that encrypting data did not completely remove the risk to privacy of possible identification. In 2003, Iceland's Supreme Court ruled in favour of Ragnhildur Gudmundsdottir who claimed that her right to privacy would be infringed if her dead father's medical records went into the DeCode health database. The court found that the risk of unwanted identification was not 100% removed by encrypting the data derived from the father's material (Law Review 2004, in Elger 2010: 15). As Greely states:

> [w]ith a population of about 275,000, no more than about 5,000 living Icelanders will have been born in any given year. An Icelander reviewing a medical record pulled up by a deCODE search will have a decent chance of identifying the source of the record by the information it contains. Such a reader might say, internally, "Born in 1962 in Akureyri, one younger sister, one younger brother . . .that must be Stefan Sverrirsson" - and then might be surprised to read of Stefan's medical history of mental illness, alcoholism, sexually transmitted disease, or other conditions (2000: 186).

In this case, the probability of identification was increased by the small size of the population. Even in larger populations, however, identification is possible and will be made

more likely by the ever increasing number of information databases, making cross-referrals both possible and likely.[9]

Third, biological samples and information can become identifying over time as new and improved technologies are developed. Currently, it is technically difficult to identify individuals from small amounts of biological material and information. However, available evidence suggests that new technologies will make technical identification easier at which time genetic anonymity will be much harder to maintain. For instance, until recently it was thought that the whole genome was needed for identification, but in 2004 Lin and colleagues showed that a small amount of genetic information could be used to identify individuals (Lin et al. 2004). This means that biological samples are more revealing than fingerprints, as a full comparator is always needed for fingerprint identification. Consider also the fact that, in 2008, Homer and colleagues showed that individuals could be identified from pooled data. Prior to this it was assumed that the pooling of data made identification of individuals impossible (Homer et al. 2008). This finding motivated the removal of pooled data on public websites, including those of the NIH and the Wellcome Trust.

Summary

Biobank donors (and this includes individuals and couples who provide broad consent to the future research use of their embryos and eggs) cannot know what genetic research they are consenting to when they donate their biological material and information to a biobank. For this reason, they cannot know if the future research they contribute to is consistent with their values. They also likely cannot anticipate future potential harms. The potential harms of donating to a biobank are complex and may include personal, familial, social, cultural and other harms for the donors as well as family and community members. Even though potential harms may have considerable impact upon family members and populations, no account of the harms to these two groups is taken when individual informed consent alone is relied upon. Further, the usual promises of confidentiality and the normal withdrawal protections are not available.

Because biological samples and information are by their very nature *shared* and *identifying*, to be ethical we cannot only think about treating fairly the individuals from whom the samples are taken. We must also think about treating fairly all present and future genetically-related persons. Given the future-orientated nature of biobanking, a 'one-off' broad consent to unknown research at the point of participation in the biobank arguably falls short of the standards for informed consent. This explains the emphasis on governance in many banking frameworks to provide additional ethical mechanisms and safeguards.[10]

In summary, the fact that genetic information is *shared* information means that individual informed consent offers insufficient ethical protection for third-parties. Likewise, the fact that biological material and information are *identifying* means that the usual methods for protecting confidentiality are insufficient.

[9] Databases that can be used as comparators are not limited to official databases, such as health records. Potentially any database (including commercial databases such as those that map shopping habits) can be used in cross-referring and triangulation.

[10] For instance, see footnote 5 on the governance practices of UK Biobank aimed to address the ethical limits of informed consent, recognizing that ethical issues will arise over time and after the point of initial consent.

Biobanks for human embryos and eggs: Additional considerations

In the 1990s, we witnessed the emergence of large-scale biobanking of human biological samples and information. Today, some 25 years later, as we continue to grapple with the ethical challenges of large-scale human biobanking of bodily tissues, we are busy creating small to middling biobanks of human reproductive tissues as these tissues move from long-term storage for future reproductive use to biobanking for future research use. An example is the RENEW Biobank at Stanford University which receives embryos and eggs from Stanford patients as well as external clinic patients (Trivedi et al. 2013; Hurlbut, this volume). The category (and perhaps physical) move from long-term storage to biobanking raises a number of ethical concerns, most prominently those arising from genetic relatedness. These ethical concerns must be taken into account for the biobanking of human embryos and eggs to be an ethical practice.

From long-term storage to biobanking

In an effort to reduce the risk of multiples and the risk of premature birth, emerging practice with IVF (In Vitro Fertilization) is to limit embryo transfer to one or two embryos. Typically, however, more than one or two embryos are created in a stimulated IVF cycle. Embryos that are not transferred are frozen and stored for later reproductive use. Many of these stored embryos are never retrieved for this purpose, however, which explains why there are collections of stored embryos in fertility clinics and long-term storage facilities around the world (with or without clear instructions for future use). To avoid having to store human embryos in perpetuity, fertility clinics typically ask those for whom the embryos were originally created for consent to discard excess embryos, or to donate them for third-party reproduction, training, or research.[11]

Recent studies suggest that the preferred option among those who agree to the disposal of their excess embryos is donation to embryo research (Blyth et al. 2011; Nachtigall et al. 2009; and Provoost et al. 2012). As an embryo research project typically only proceeds when there is a sufficient number of embryos available for research, this has meant that, in jurisdictions that prohibit the creation of embryos for research, embryos originally created for reproduction and later designated for research remain in storage in anticipation of such use which may be long after the requisite consent was obtained. There is an important change in status, however. The embryos are no longer in long-term storage for future reproductive use (for self or a third-party), but are biobanked for future research use. This change in status may or may not entail a physical transfer from one storage facility to another. The manner in which human embryos typically come to be in a biobank (by this name or any other) marks an important difference between the biobanking of bodily tissues and the biobanking of human reproductive tissues. Whereas bodily tissues that are biobanked go from the body to the biobank, reproductive tissues that are biobanked typically follow a more circuitous route,

[11] In many jurisdictions, individuals are invited to provide a broad consent to embryo research. Within these jurisdictions, some biobanks will streamline the options. For example, RENEW Biobank at Stanford University identifies two specific streams of embryo research (early human development and genetic reprogramming and/or production of cell lines) and donors can contribute to one or both classes of research. See for example, a sample consent form at https://med.stanford.edu/content/dam/sm/hesc/documents/donations/tissue/8-_External_Clinic_Embryo_Cryo_ResearchConsent14.pdf. In other jurisdictions, most notably Canada, broad consent is not an option. Consent regulations require consent to "a specific research project, the goal of which is stated in the consent" (Canada 2007).

passing through long-term storage for potential future reproductive use by the original provider or a third party. It is only when there is no intent to pursue a reproductive project that human embryos may become eligible for research, and with proper consent be added to the reproductive tissue biobank.[12]

In the coming years, there may be a similar trajectory for the biobanking of frozen eggs for future research use. This is because a majority of the eggs currently in storage for the egg provider's own reproductive use very likely will not be used for reproduction (either by the women who originally stored them or by other women). If the eggs are not to be used for reproduction, they can be donated for training, or research, or they can be discarded. If we extrapolate from practice with respect to the disposition of frozen embryos, we can anticipate that women with stored eggs will have a preference among these options for donation to research. This suggests that in the future, we can anticipate increased numbers of eggs moving from long-term storage for reproductive use (by either the egg provider or a third-party) to biobanking for research use.

Below we consider possible significant differences between the biobanking of reproductive tissues and human tissues in general, such as, greater emotional attachment to embryos and eggs because of their potentiality (the real and imagined possibilities they represent). Second, we consider whether there are important differences between long-term storage of reproductive tissues for future reproductive use (whether by the providers or third parties) and biobanking these tissues for future research use. Third, we close with a comment on how these considerations connect with the *shared* and *identifying* nature of genetic information.

The type of tissue: Life containing, life potential, life saving

Are reproductive tissues a *type* of material that is significantly different from more routinely biobanked tissues? It seems to us that there is no definitive answer to this question. The answer very much depends on both donor attitudes, and on what the tissues are to be used for.

Of particular relevance is the extent to which the prospective donors of reproductive tissues believe these tissues contain 'life' or the 'potential for life', and the extent to which they perceive these tissues as potentially 'life saving'. This is found to be the case in a number of studies. For instance, Badadur and colleagues, drawing on numerous previous studies, particularly Erica Haimes and Ken Taylor (2009), suggest that the acceptability of tissue donation is connected to perceptions of what is 'valuable' and what is 'waste'[13] and whether tissues are "seen as maintaining life" or "containing life" (Badadur et al. 2010: 871). For those who hold such assumptions, "blood donation is considered a lesser sacrifice than donating an organ …[and] eggs are presented as easier to donate than embryos because they contain 'less life'" (Badadur et al. 2010: 873). If this is the case, then it is likely that for many the donation of embryos for research purposes will be more significant than the donation of

[12] Some countries permit the creation of human embryos for research use (for instance, Australia, Singapore and UK allow the creation of research embryos (Hyun, 2014: 28)). In these countries it is possible that embryo providers would make a direct contribution to a human embryo biobank, in which case there would be clearer trajectory from the provider's body to the biobank.

[13] Many cite *Moore v. Regents of the University of California* as a point of profound change regarding what is 'waste' tissue. Before the genetic era, diseased and discarded tissue was *res nullius*. In the genetic era, all such tissue became potentially valuable. It follows that if donors realise the value of their reproductive tissues, they may be less willing to donate embryos and eggs to a biobank, particularly if donation is to a commercial rather than a public sector biobank.

eggs and, in turn, the donation of embryos and eggs for research purposes will be more significant that the donation of other bodily (non-reproductive) tissues.

Following the 'potential for life' line of reasoning, embryos and eggs are not quite the same insofar as embryos are generally regarded as having more 'potential for life'. This does not mean that individuals or couples endorse pro-life views and equate embryos with persons. In fact, embryo donors report views of embryos that span the spectrum from "embryos as persons" to embryos as a "bunch of cells" (Haimes and Taylor 2009); and, between these ends of the spectrum, there are those who view embryos as "potential persons" and "protopersons" (Thompson 2005). Moreover, cultural and individual understandings of what embryos are and what they represent are not static. For example, as Giulia Zanini observes, "the same embryos may stop being reproductive and lose their sacred character when they are not considered as leading to a pregnancy any longer" (2013: 92). Some embryos that are no longer perceived in terms of 'potential for life' may come to be seen as 'life saving', as when it is anticipated that the embryos will be used in embryonic stem cell research.

Despite the divergence of stated views about the nature of the embryo, the fact that individuals and couples struggle to make decisions about what to do with stored embryos they do not wish to use for their own reproductive purposes, makes it reasonable to infer that very few individuals or couples find this an easy decision. Indeed, the data about how individuals and couples delay decision-making about what to do with their stored embryos are revealing; it is estimated that over 70% of people fail to make a decision years after their treatments (Nachtigall et al. 2005). In addition, "many couples actively avoid the decision by not keeping in contact with the clinic" (MacCallum and Widdows 2012: 279). This suggests that even though some say embryos are a 'bunch of cells', they appear to have a significant attachment to them manifest in a passive approach to decision-making regarding the fate of unused stored human embryos. Rather, significance is connected to the potential that the embryos hold, or held, as potential future children with whom they could have had a relationship and who would have been part of their family.

Thus, while most individuals and couples with embryos in storage do not regard stored embryos as persons, they do regard them as significant and they are attached to them (De Lacey 2013). Studies that point to this emotional connection, note that "leftover embryos – often affectionately termed 'embies' or 'frosties' by infertile couples – are sentimental objects for intended parents" (Madeira 2010: 320). This is perhaps not surprising given that fertility clinics encourage women undergoing IVF to develop an "emotional connection to embryos by giving intended mothers pictures of transferred embryos and encouraging them to watch the transplantation procedure on an ultrasound screen – and perhaps even giving them an ultrasound picture of the newly transferred embryos 'at home' in the uterus" (Madeira 2010: 319-320). And, for some women their stored embryos "may seem like 'sisters' or 'brothers' to already-born children conceived through the same cycle" (Madeira 2010: 322), or like "part of the family" (Cattapan and Doyle, in press). In this way, embryos come to be viewed as significant in a way that other bodily tissues are not. This attachment is about potentiality, relationships and family structures.

Following this line of reasoning, it seems likely that women might also have some (though perhaps less) attachment to their stored eggs. Indeed, limited available evidence suggests that women who undergo hormonal stimulation and egg retrieval for the express purpose of selling their eggs think about what happens to them and about potential future children. For example, a number of Romanian women who sold their eggs for third-party reproductive use

reported thinking about their 'babies', and when asked specifically about what they thought they were selling, one women said that "she thought about 'her babies' once in a while" (Nahman 2008: 68). We know of no empirical evidence about the views of women who originally had eggs in storage for their own reproductive use and later chose to donate or sell these for third-party use. We expect it is too soon to have any such information. It stands to reason, however, that if women who sell their eggs feel some attachment to them, despite the fact that these eggs were never intended for their own reproductive use, then women who originally produced and stored eggs in order to have children themselves might well feel some attachment to their eggs.

The use of reproductive tissues: Reproduction or research?

Many jurisdictions have no embryo storage limits and this has resulted in the stockpiling of stored embryos (e.g., Canada, United States). In other jurisdictions, embryo storage limits have been introduced (e.g., United Kingdom, Australia and New Zealand). In jurisdictions with storage limits, individuals and couples with unused embryos in long-term storage can avoid decision-making about what to do with their embryos by simply allowing the maximum storage period to lapse. In the alternative, if they have a preference with respect to what should happen with their unused embryos, they can act as would be required for individuals and couples in jurisdictions without storage limits. For example, they can actively choose to discard their stored embryos, or they can choose to donate them for third-party reproduction, for training, or for research.

Some individuals and couples emphasize kinship. Among these individuals and couples are those who consider it unethical to allow a 'related child' to be born to another couple, and those who simply do not want to know that their "'eventual biological children'… [are] 'out there' in the world" (Cattapan and Doyle, in press). For such individuals and couples, the 'potentiality' of embryos is not about them fulfilling their life potential and becoming a child, but about possible future relationships and kinship ties. Thus, what matters is potential connectedness and meaning *for them*, rather than meaning in general. For others, genetic relatedness is significant, even if less important than other factors relevant to family-making such as intentionality, gestation and social care. All of these individuals and couples are concerned, in one way or another, about creating kinship ties (of which they and their family might be unaware, and that might only be revealed to them at a later date). These individuals and couples would not choose to donate their unused embryos for third-party reproduction.

By contrast, other individuals and couples attribute moral status to human embryos and consider them potential persons. Among these individuals and couples are some who consider embryo research unethical as it results in the destruction of embryos. Of note, however, is the fact that those who emphasize the moral status of embryos do not always act as one might expect and donate their embryos for third-party reproduction. Indeed, though "'one might assume that viewing embryos as 'persons' or potential persons would make donation a more attractive proposition than allowing embryos to be discarded and thus wasting potential life… the opposite pattern is seen" (MacCallum and Widdows 2012: 278). In fact, as Eric Blyth and colleagues note "*relinquishment of embryos for family building is frequently – although not invariably – the least favourite alternative*" (2011: 267; emphasis in original). Of course, some individuals and couples do donate their stored embryos for reproductive purposes, and among them are those who describe the transfer as an adoption (not a donation); their intent is to ensure that their embryos are not orphaned. This perspective, however, seems less common than one might expect. Instead, evidence suggests

that kinship ties weigh heavily in the decision-making about the disposition of stored embryos. In general terms this has led to the suggestion that a key factor in decision-making about what to do with unused stored embryos is whether 'life ethics' or 'kin ethics' is most influential in the individuals' or couples' decision-making (Zanini 2013, drawing on Collard and Kashmeri). These perspectives are reported by Zanini who recounts in-depth interviews with Linda and Camilla – women with embryos in storage. According to Zanini, Linda:

> defines parenthood according to intentionality, love and care rather than by genetics or pregnancy. Linda values embryos in the same way in which she values reproductive cells and pregnancy for the indispensable place they occupy within the reproductive process that she has undergone and confers all of them the power to lead her to parenthood. On the contrary, she does not think of embryos as of her own children-to-be since she does not perceive the ontology of embryos as being related to parenthood. Embryos are rather understood as necessary steps to kinship formation. (2013: 100)

In contrast, Camilla exhibits some aspects of what one might think of as 'life ethics'. She thinks that in some sense embryos turn into a 'life' at the moment of implantation and she speaks of 'embryo adoption' during her interview. As Zanini reports, Camilla believes that:

> embryos which have been relinquished by other couples may share their genetic material with other existing embryos or children. Moreover, she [Camilla] does not feel comfortable with the fact that the embryos had been produced for the reproductive intentions of other prospective parent….Camilla imagines the potential children resulting from implanting these embryos to have some genetic siblings somewhere and to share with them some sort of family history (2013: 102 -103).[14]

And yet, ultimately, Camilla does not choose embryo donation for reproductive purposes. This suggests that emotional attachment and care do not ensure that stored embryos will be donated for reproductive purposes thereby giving them a chance of life. Rather, the emphasis seems to be on protecting kinship networks. In reporting on Robert Nachtigall's research, Jody Madeira notes that, "donating frozen embryos to other infertile couples was … an unpopular option because it entailed two difficult emotional processes: surrendering embryos to which couples were emotionally attached and accepting that they may develop into someone else's children, in effect adopting out one's own offspring" (2010: 326).

This discussion suggests that the future *use* of reproductive tissues as compared with other bodily tissues is significant. This has important implications for the move from long-term storage of reproductive tissues to the biobanking of these tissues. If individuals and couples are uncomfortable with donating embryos for reproduction, and can see and value the 'life-saving' potential of embryos they may prefer to donate embryos to research to "improve the prevention, diagnosis, and treatment of illness and the promotion of health throughout society" (UKB EGF 2007: 3). Indeed, individuals and couples with embryos in storage tend to choose donation to research in order to use their embryos in some way, to advance some

[14] Interestingly Camilla distinguishes between the genetic link with one donor and with both donors (as they would not be full siblings to her children). In this case, relinquished embryos represent the highest degree of kinship relatedness as they embody the reproductive parental intention of two previous prospective parents and are possibly genetically linked to them and their offspring" (Zanini 2013:104).

measure of altruism, and to avoid the "entangling kinship ambiguities" of donating to the reproductive purposes of others (Cattapan and Doyle, in press; Nachtigall et al. 2005).

Reproductive tissues kinship and identification

Thus far we have considered how donor perceptions about the *type* of tissue and how it is to be *used* are important for the biobanking of human embryos and eggs. This brings us full circle to our earlier discussion about the *shared* and *identifying* nature of genetic information and the long-term nature of biobanking.

Embryo and egg donors are aware and concerned about both the shared and identifying nature of reproductive tissues. They worry about their children 'sharing' genetic material with other potential children and they worry about such links being revealed in the future (an identification worry).[15] The question is whether these concerns about donation for reproduction are continuous with concerns about biobanking more generally, or whether they are radically different and raise additional ethical worries. This is the question to which we now turn our attention.

First, the notion of *shared* that is in play in biobanking reproductive tissues is significantly different from the notion of shared that is in play in discussions of possible genetic siblings that might result from the donation of reproductive tissues for third-party reproduction. With the donation of embryos and eggs to a biobank no person is created, so no new or additional kinship bonds result. There are no new shared relations. What is shared in biobanking is genetic material that reveals shared susceptibilities and characteristics. Biological samples and information stored in a biobank do, of course, reveal kinship links; and there has been much discussion about the problems that might arise with this, as when non-paternity is revealed. Of greater concern, however, is what is revealed by the stored samples and information and whether such revelations are pertinent to genetically related others. It is possible that genetic research could have implications for genetically related persons, for instance, existing children from the same cohort of embryos, or future genetically related persons. Whether embryo and egg donors would consider potential revelations from this type of sharing important, in a similar way to revelations of shared genetic material from reproductive purposes, is unclear. At first glance this seems unlikely, as these are certainly different understandings of sharing. They are connected, however, and therefore merit some consideration when it comes to the biobanking of human embryos and eggs.

Second, the potential for identification applies here as it does in other biobanking scenarios. Again, whether embryo and egg donors would consider this significant requires further investigation. Given that many donors already choose to reject donation for third-party reproduction to protect their current family, it may be that they will have more identification worries than donors of other types of tissues. We know that embryo and egg donors are particularly concerned about impact on relationships, and perhaps they will be particularly concerned about this with biobanking as well. It may also be, of course, that many current biobank donors would be more concerned if they understood the implications of the limits of informed consent and confidentiality, and realised that their decision to donate to a biobank for research use might have implications for related others and future generations.

[15] Genetic relatedness can be revealed between two genetic-siblings or half-siblings by comparator testing (say of hair) which can be done on-line or by comparison with genetic databases.

Conclusion: Ethical biobanking of embryos and eggs

There are a number of ethical challenges with human biobanking in general and biobanking of human embryos and eggs in particular. Many of these challenges arise from the *shared* and *identifying* nature of genetic materials and information, and the nature of biobanks as large-scaled and long-lived endeavours. Our discussion points to some practical issues that require further attention. In particular, relying on individual informed consent alone is not sufficient, and promising confidentiality is problematic. For the biobanking of human embryos and eggs to be an ethical practice it is imperative that donors understand the *shared* and *identifying* nature of genetic information in the event that related potential harms are relevant to their decision-making.

Further, our discussion has raised a number of ethical concerns surrounding the potential move of reproductive tissues from long-term storage to biobanking (a move that may or may not include a change in location), owing to the actual and symbolic importance of these tissues for prospective donors. Considering the views of embryo and egg donors expressed to date, we should explore whether the concerns they raise with respect to donation for reproductive purposes extend to donation for research purposes and more specifically to biobanking. It may be that the contexts are sufficiently different that concerns about emotional attachments are also different. If so, then biobanking may prove to be popular option for unused human embryos and eggs in long-term storage. In which case we should turn our attention to the governance and oversight of biobanks for human embryos and eggs, perhaps with particular attention to the benefits and limitations of centralized versus distributed biobanking of these tissues.

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