

We're not in it for the money—lay people's moral intuitions on commercial use of 'their' biobank

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Abstract Great hope has been placed on biobank research as a strategy to improve diagnostics, therapeutics and prevention. It seems to be a common opinion that these goals cannot be reached without the participation of commercial actors. However, commercial use of biobanks is considered morally problematic and the commercialisation of human biological materials is regulated internationally by policy documents, conventions and laws. For instance, the Council of Europe recommends that: “Biological materials should not, as such, give rise to financial gain”. Similarly, Norwegian legislation reads: “Commercial exploitation of research participants, human biological material and personal health data in general is prohibited”. Both articles represent kinds of common moral intuitions. A problem, however, is that legislative documents are too vague and provide room for ample speculation. Through

the use of focus group interviews with Norwegian biobank donors, we have tried to identify lay intuitions and morals regarding the commercial use of biobanks. Our findings indicate that the act of donation and the subsequent uses of the samples belong to two different spheres. While concerns around dignity and commodification were present in the first, injustice and unfairness were our informants' major moral concerns in the latter. Although some opposition towards commercial actors was voiced, these intuitions show that it is possible to render commercial use of biobanks ethically acceptable based on frameworks and regulations which hinder commodification of the human body and promote communal benefit sharing.

Keywords Benefit sharing · Biobanking · Commercialisation · Commodification · Focus group research · Lay perspective

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Introduction

Globally there are several hundred large biobanks, such as the UK Biobank, BioBank Japan and the Norwegian HUNT biobank which all are resources for medical research (UK Biobank 2009; CGM Riken 2011; NTNU 2011a, b). Substantial amounts of public and non-profit research funds have been used to build up these resources (Hall 2006; Brice 2009; Cookson 2010; Research Council of Norway 2010; Walsh 2010). The ultimate objective of establishing these biobanks is to produce knowledge that forms a basis for better diagnosis, treatment and prevention of disease, as well as firmer knowledge-based health promotion (UK Biobank 2007). Various actors have depicted the contents of biobanks, which are human biological material and health-related information from hundreds of thousands of

participants, as ‘gold deposits’ (Hoeyer 2005; Fugelsnes 2009; Kuras 2010; Roel 2011). Kierulf (2006) even describes biobanks as sources that can be ‘mined for decades’, but will the ‘pure gold’ shine if it does not enable knowledge production?

The involvement of commercial companies seems crucial for realising the potential within biobanks to contribute to better diagnostics and improved drugs (Research Council of Norway 2008). Commercial companies have the funds, the expertise and the experience to take a potential product from bench to market (Policy and Medicine 2011).

On behalf of the Norwegian Ministries of Education and Research and of Health and Care Services, The Research Council of Norway (RCN) published a report in 2010 on the potential commercial use of biobank resources. In this RCN report the idea of a national company which could facilitate commercial activities based on Norwegian biobank resources is endorsed. Here HUNT Biosciences Ltd. (HBAS) is promoted as a viable prototype for such activities (Research Council of Norway 2010). HBAS is a Norwegian publicly owned company established in 2007 (HUNT Biosciences 2011; NTNU 2011c). It aims to facilitate private actors’ access to the Norwegian Nord-Trøndelag Health Study’s (HUNT) resources. HUNT is publicly run in an academic setting. Its collection has been gathered over the last three decades and includes a biobank: the HUNT Biobank.

Aspirations of commercial use of public and non-profit research are far from unique for the biobank sector. They are rather a part of a general emphasis of post-academic knowledge transfer from various research communities to society at large. Commercial use of biological material and health-related information, donated by individual participants, has the potential to benefit science and subsequently the public good. On the other hand, it also raises ethically complex and challenging issues. For instance, what type of commercial use could or should biobank resources be used for in order to bring about substantial societal and economic benefits? The establishment of deCODE, the commercial, US-owned, Icelandic biobank project, generated strong ethical controversy internationally (Rose 2006). deCODE received critical attention not only from within the expert arena of bioethics but also from international media and scientific communities as well (Palsson 2008).

Meanwhile, commercial utilisation of publicly or non-profit funded biobanks, established in the public and academic arena, has not achieved the same attention. We expect this to change, as the prospect of commercial exploitation of large population-based biobanks is an important issue that at present faces biobank stewards, society and biobank participants.

Biobank commercialisation and the law

Why does commercialisation of biobanks seem to be strictly regulated while at the same time commercial use is a wanted development, as exemplified by the launch of HBAS? Various legislations, including the Norwegian legislation, prohibit the “Commercial exploitation of research participants, human biological material and personal health information” (Ministry of Health and Care Services 2008). The Council of Europe’s Convention on Human Rights and Biomedicine (Oviedo Convention) and its additional recommendation Rec (2006): 4 have similar instructions (Council of Europe 1997, 2006). The bans on the commercialisation of the human body and its parts represent a restrictive stance and seem to be motivated by fear of exploitation, injustice and commodification as summed up by Schweda and Schicktanz (2009).

“Though it is not always clear what commodification is thought to imply, a morally degrading transformation from something intrinsically human [beyond commercial usage] to an object of ownership seems to be at stake in most accounts”, Hoeyer (2007, p. 327) suggests. Or as Seale et al. (2006, p. 25) express: “Commodification is frequently regarded as violating personal, social and community meanings for bodies”. These ideas have been highly visible in the ethical debate on the transfer of human organs (See e.g. Andrews and Nelkin 2001; Healy 2004; Rothman and Rothman 2006; Sharp 2009) and have extended into the wider realm of human biological materials (See e.g. Sharp 2000; Holland 2001; Ministry of Health and Care Services 2001; Godard et al. 2003; Irish Council for Bioethics 2005; Thomas 2006).

The essence underpinning prohibitions against buying and selling organs, tissue and blood is a perception of threat to personhood, human dignity and worth. The Norwegian pre-legislative official report on biobanks (Ministry of Health and Care Services 2001, p. 69) explains that materials drawn from an individual’s body and stored in a biobank should be treated with the same respect and dignity as the donor. While the Irish Council for Bioethics (2005, p. 7) writes:

Commodification of human beings is a violation of human dignity, which reduces the individual to the status of a mere object. In order to safeguard the dignity of research participants, biological material should not, be bought or sold or give rise to financial gain

As shown, the commercial prohibitions in legislation and guidelines do not only pertain to body parts as organs, but include the broader term ‘human biological materials’. Against this, as recently addressed by Lenk and Beier (2011), it is interesting to note that some types of human

biological materials, such as breast milk, plasma and plasma products as well as various tissues and cell lines are already treated as commodities in the marketplace of health and research. This raises a tension between the prohibitions made and practises already in place. In addition, it might render new developments either in the use of human tissue in treatments or in medical research where commercial actors are involved problematic.

Scepticism amongst donors?

Donor contribution is a crucial prerequisite for biobank research and knowledge of potential donors' views on these issues is important. In general, public awareness of biobanks in Europe is low, although somewhat better in the Nordic countries (Gaskell and Gottweis 2011). Hence, issues concerning biobanks or biobank research are not topics that people in general have discussed or given much consideration.

Understanding pre-articulated beliefs and intuitions on commercial exploitation of biobanks has intrinsic value in bioethics. In addition it will indicate whether we can anticipate lay people's acceptance or rejection of the commercial use of biobanks, if this will lead to distrust in general and reduced participation in particular.

Several scientific studies have explored public attitudes toward biobanks and biobank activities. They report varying degrees of scepticism towards commercial use and for-profit organisations' access to biobank resources (Stegmayr and Asplund 2002; Skolbekken et al. 2005; Hoeyer and Lynøe 2006; Kettis-Lindblad et al. 2006; Nilstun and Hermerén 2006; Haddow et al. 2007; Webster et al. 2008; Trinidad et al. 2010; Nicol and Critchley 2011). While Stegmayr and Asplund (2002) reported that Swedish biobank donors sanctioned industrial research, others registered marked opposition from lay people against the access of commercial companies to diagnostic or research samples (Nilstun and Hermerén 2006; Tupasela et al. 2010). In a qualitative study of potential donors' views on the Generation Scotland Project, Haddow et al. (2007) identified resistance towards commercial companies' involvement. But nuanced attitudes were voiced including pragmatic acceptance of pharmaceutical industry involvement. These studies show that there is scepticism amongst lay persons towards commercial use of biobanks but it is far from unanimous and the basis for this scepticism needs further exploration.

In Norway commercial utilisation of biobanks has, to a certain extent, been debated in expert arenas. The ethical challenges related to commercial biobanking in general or to HUNT Biosciences in particular, have not evoked public controversy (Ursin 2010). Despite the lack of a larger public debate earlier findings (Skolbekken et al. 2005)

indicate that the prospect of the commercialisation of biobank research creates uneasiness amongst potential and actual HUNT participants. This is also something the organisers of HUNT Biosciences have been sensitive towards and they state that they offer "a professional interface with industry and facilitate commercial use without compromising the interests of the donor population" (HUNT Biosciences 2011).

Articulation of ethical concerns by the use of focus groups

Commercial utilisation of biobanks is not a clear-cut ethical issue. According to the legal reasoning and the general scepticism referred to above, ethical problems pertaining to commodification of the human body and its parts may induce resistance among biobank participants towards commercial use of this resource. But it is not obvious what is at stake and whether there is something to disagree about. The 'ethical problem' here is much vaguer than, for instance, in high-profile ethical issues like surrogacy, stem cell research or genetic testing. Our common morality has no clear and distinctive options or problem descriptions to serve us but we still 'feel' that there is something amiss.

Our motivation for an empirical study, then, was to dig deeper into this arena of pre-articulated beliefs and intuitions on the meaning of human biological material and commercial use in biobank settings. As the philosopher Charles Taylor (1985, p. 36) has stressed, "...articulations are attempts to formulate what is initially inchoate, or confused, or badly formulated ... To give a certain articulation is to shape our sense of what we desire or what we hold important in a certain way". We believe that focus groups are a suitable arena where an articulation process can take place, and where we can hopefully come closer to what a common 'we' hold important.

The logic of laypersons in terms of biobank experience is relatively unexplored. In order to learn more about their insights or wisdom attached to vague feelings and emotions we engaged them in focus group discussions. Following Kass (1997) and his 'Wisdom of repugnance', we sought deliberations which could lead to a better articulation of 'yuck-reactions' and what is ethically at stake when biobanks are commercially utilised.

Methods and materials

To study lay people's intuitions, beliefs and moral reasoning we conducted semi-structured focus group interviews (Morgan 1993). As Schweda and Schicktanz (2009, p. 1131) describe, this strategy is "an established tool for investigating common sense beliefs and public topoi on a

general level". We involved lay persons from the county of Nord-Trøndelag in Norway who, in general, are well acquainted with the HUNT study and its large population-based biobank through HUNT's long history, high local awareness and political support (NTNU 2011a).

Approval

This study was approved by the Norwegian Data Inspectorate via the Norwegian Social Science Data Services (NSD) who handles the statutory data privacy requirements in the research community in Norway.

Focus groups: participants, recruitment and group settings

Biobanks are not widely discussed in the public arena, and the ethical problems are seldom clearly articulated. We therefore strategically recruited lay people from Nord-Trøndelag, the locus of HUNT, who we expected to be familiar with biobank research/participation. In addition, we involved people with varied backgrounds regarding knowledge and/or experience of patient relationships, commerce, academic settings and research. To achieve this we recruited people from various districts in the county who either belonged to a patient or an idealistic public health association, worked at a university college or an industrial company. This was done in order to increase the likelihood that participants would reflect on and discuss topics related to health, industry, politics and ethics. The recruitment process was done via key informants. An initial invitation letter was sent to them which they subsequently distributed to potential participants.

We tried unsuccessfully to recruit younger people from student groups at the three different university college campuses in the county, but did not get sufficient response to set up focus groups from this segment of the population.

Although our recruitment was broad and without any requirements for previous biobank participation we ended up with persons that had participated in HUNT either on one or more occasions. Two of the participants had actively withdrawn from the biobank project after their initial donation.

Prior to the group discussion each participant received information including some facts about the HUNT study and the framework for HBAS (Steinsbekk et al. 2009), an information leaflet for the HUNT 3 study (NTNU 2011d), and a letter with a short description of the topics and examples showing the types of questions that would be discussed.

In 2010 we ran eight focus group interviews with 45 participants. Each group discussion was held at locations such as a community centre, local hospital, college campus or workplace. A total of 12 men and 33 women in the age range of 30–80 participated. Each focus group session lasted for 2 h and was moderated by two facilitators out of our group of four researchers. One researcher participated in all the sessions. We used a topic guide and each subject was introduced with the use of a power point presentation.

In order to introduce some possibly familiar ethical challenges of commercialisation into the discussions and to facilitate the subsequent talk about commercial use of 'their' biobank, we chose the topic of commercialisation of blood and organ donations as our point of departure. See Table 1 for an outline of the topics, how they were introduced and the main questions posed. We also discussed other topics such as trust, privacy and data protection, but the findings from these are not reported here.

All the discussions were digitally recorded, with a consent from each participant, and subsequently transcribed into full text and anonymised. We translated statements used in this paper to English in a manner which reflects the actual wording used by the participants with some adjustments to retain content where needed.

Table 1 Short outline of the data collection framing

Topics	Commodification of the human body and its parts	Commercial utilisation of biobanks
Headings	The market and the human body	HUNT in use
Introduced by	Illustrations: Venepuncture and blood collection Logo for organ donation Breast feeding	Information about HUNT Biosciences' framework were read together Structured description of three different potential commercial HBAS projects were handed out
Initial question	What is your opinion on the possibilities of making money on human biological material?	What are your opinions on these proposed HBAS projects?
Follow up keys both topics	Acceptable/not acceptable practices Limits and challenges Reasoning for their views and reactions Articulating how the issue should/could be handled	

Coding and analysis

We analysed the interviews in an inductive manner in search of themes. The process was informed by Systematic Text Condensation, which was inspired by Giorgis and modified by Malterud (2003). In addition, insights from Krueger (1998) on analysing focus group materials with an emphasis on thematic analysis were used. According to Haimes (2002, p. 99), these “could be seen as providing descriptive ‘facts’ to go alongside normative statements”.

Each member of the research team read the transcripts and we identified and discussed the emergent themes. The transcripts were revisited several times and the analysis led to condensations of ethically relevant themes into concepts which are presented and discussed in this paper.

Findings

In this part we present and comment on our findings while a broader in-depth analysis and discussion is given in the next part. As presented below, two distinctly different sets of moral concerns emerged from our focus groups.

Selling oneself is morally problematic

When entering the discussion of ‘The market and the human body’ our discussants immediately drew upon issues of commodification of the human body and its parts. In particular, the possibility of a donor selling his or her own organs was debated. This topic raised uneasiness and was described with word or phrases such as: ‘unpleasant’, ‘unhealthy’, ‘no, no, no’, ‘does not sound good’, ‘immoral’ or ‘disgusting’.

There was no opposition to blood or organ donations in themselves, it was introducing ‘the market’ that was problematic. A major concern articulated in the groups was that financial incentives for organ donors could lead a person to make the decision to donate based on wrong premises. Issues of greedy intermediaries, unregulated ‘black markets’ and exploitation of underprivileged persons also emerged.

FG8: R3: In my family a person received a kidney. It was a boy who died and she got the kidney and ... I have to say that I think it is great. [Universal agreement in the group]. But if she had received it from a developing country, and paid a lot of money, I would not think that it was great.

M1: What lies behind this?

R3: ... dealers and greed, it is, real buying and selling. It will be like trafficking of drugs.

To attempt to identify whether there were some additional concerns, we as moderators tried to set exploitation and unfair enrichment aside. We suggested alternative ways to organise the sale of organs or blood, such as via the publicly owned and run hospital sector in Norway.

FG9: M2: But is it the exploitation that is the problem? ... What about a system where the government pays you a hundred pounds per kidney?

R4: Oh, I think that sounds terrible. That they offer money for your kidneys.

R1: Actually I think it sounds a bit convenient.

R4: No, I do not like it.

R2: No, I completely agree.

M2: Why not?

R4: I think it sounds unpleasant, that one starts to sell body parts.

R1: [jokingly] Come up with a factual argument now – unpleasant?

R4: No, I don’t know—it’s just sort of – like a feeling.

When probed it was not easy for the discussants to articulate the rationale behind their normative judgements. Although they tried, several commented that it was difficult to put their opinions into words. They said that some things just did not seem or feel right, indicating that their views were grounded in some basic values, feelings and traditions, something they ‘just had’—‘gut feelings’.

FG6: R1: ... so it’s a, well ... maybe there are some kind of values within us that says that we as humans have an intrinsic value that goes beyond dead things. So it is possible there is something inherent, within us. In our blood?

FG9 R1: ... and we are raised that way, that it should not be paid for.

When focusing on blood, financial gain for donors was also here, for the most part, viewed with suspicion, while compensation for the donation of breast milk was more readily accepted. To be paid for a blood donation in a state-run system sounded like a good idea to some, whilst others could, to a certain extent, support compensatory strategies if a donor had some sort of financial loss when donating blood for research or transfusion. As exemplified below this view was fundamentally opposed by some participants expressing that no form for payment, either monetary or as other gifts, was acceptable. The overall notion in all the groups was a resistance towards implementing monetary incentives in donation settings whether they talked about organs for transplants or blood to HUNT.

FG6: R3: No, I think it is reprehensible ... I should give away that blood without receiving a mug or a

towel or money. Well, I do not know how much they get for eggs or sperm nowadays, but I think ... kidneys, heart, lungs and so forth – where would we draw the line? ... if I want to give away my blood sample that's okay, but it should not be sold, because then we are immediately in the market sphere.

The donation of human biological materials, especially organs, can be seen as fundamentally problematic in itself, that one violates one's self when donating, as one discussant stated:

FG7: R4: Yes, I have donated my body ... but it is something completely [different] ... I do not want money for it. It would almost feel like an insult, a type of scorn if I did it for money ... It is something moral here.

Since what is donated is essential and can potentially heal or even save other people's lives this act can be less wrong, the objectification can be lessened or cancelled out, when the act of donation is kept pure, free from monetary influences, as the ultimate 'gift of life'. Thereby we as donors are able to restore our relationship toward ourselves by being able to give something that in essence is not ours to give.

As described, it was difficult for many to explicitly express the reasoning behind their negative views on the possible introduction of the market in the donor setting. The words often used were value-laden and much of the reasoning based on feelings and can be termed as 'yuck reactions'. It is possible, though, to interpret the expressions of uneasiness and aversion as based on threats the market mechanisms are perceived to put on human dignity and the respect for human worth. The following statement can therefore be claimed to represent a shared sentiment found in the groups:

FG6: R4: I am afraid it will do something with human dignity if we reduce people to a commodity that can be cut into pieces and sold bit by bit.

This is what we signed up for

When a couple of possible scenarios of commercial utilisation based on the HUNT and HUNT Bioscience case were described, the immediate and universal responses can be summed up by the following statement:

FG3: R7: This is what we signed up for when we participated.

The discussions that followed in all groups unanimously agreed that the proposed HUNT Biosciences projects definitely were undertakings that they, as donors, could

endorse. It became very clear that the projects themselves were uses of the biobank resource that they had envisioned. Development of diagnostic tests or knowledge production for the possible advances of better therapeutics and hopefully also prevention were exactly what participants hoped for when making their donations. Opening the biobank for private actors, however, was a different matter.

Here there were a diversity of reflections and thoughts that can be seen as ranging from strongly opposing voices to ones of full support.

FG8: R4: ...in fact – I did not consent to commercial exploitation. It was for research.

FG3: R7: We're not really interested in them getting rich – those who flood us with medicine ... that is not what's important for us.

When asked to substantiate the scepticism demonstrated towards commercial utilisation the prominent reactions pointed towards the possibility of someone achieving unjust financial gain. This was clearly articulated in all our discussion groups especially with a pronounced scepticism towards the pharmaceutical industry.

FG4: R6: ... the added value ends up in the accounts that are already overloaded, or are there any guidelines ensuring that it will benefit the general public? All them pharmaceutical companies – they are not known for altruism

FG8: R2: We envision some sharks at the top and I have heard very much about that industry ... They're almost billionaires ... it does not taste good you know...

R4: But it's not only that. It is that it's something that is ours, that we have given away – donated to research.

R2: And not for someone to make money on it!

R4: No, right.

R5: That's the point.

How this commercial utilisation is managed and that it includes strategies which lead to contributions to common goals and goods were seen to be crucial. The potential enormous revenues to private companies were seen as challenging and potentially immoral as only a few, already strong and resourceful organisations, would harvest the financial benefits based on a common good.

An inherent structure of commercialism is the drive to protect ones investments and to maximise potential gains. Our respondents expressed that within medicine and health this can lead to the development of unnecessary or even unhealthy products.

FG4: R1: Actually – research should lead to reduction of the use of medication. But will we get that far?
 R6: No, because there is no commercial interest in the reduction of drug use.

Others questioned why product discovery and development could not be done in the public sector or at least within a non-profit organisation.

FG6: R2: My thoughts on this are very influenced by the fact that I think the public sector in Norway has a poor research strategy, I think it's really bad that we have left, for example, the area of pharmaceuticals to private industry ... so I think it's bad that we have organised ourselves in this manner, that much of this important research is on commercial hands.

These views coincide with the high trust Norwegians in general place in governmental and non-governmental not-for-profit organisations. The business and commercial sector has an overall lower standing. This is reflected in the Edelman's trust barometer from January 2011 (Dinamo 2011), which, in addition, shows a particular distrust in the pharmaceutical industry.

On the other hand, voices clearly endorsing HBAS, the commercial strategy chosen for HUNT and 'their' biobank were also heard:

FG3: R7: If they are not allowed to do research on our blood samples then travelling around and gathering them are pointless. They must be allowed to use them.

FG4: R3: I agree, they should go down that road – actually ... otherwise there is no point in collecting, there's no point in sitting on a million blood samples if they are not used.

The supportive responses reflected pragmatic views; that commercial utilisation is 'a part of the zeitgeist' or 'that this is how the world operates'. They also acknowledged commercial actors' part in taking novel medical products from 'bench to market'. It was of utmost importance that the biobank resources are actually utilised.

The positive intuitions also included an endorsement of the framework of HBAS. That it is publicly owned and locally based. Part of its mission is to channel some financial gains back to the local community via health initiatives and research. Others pointed out, that biobank research carries large financial costs and that the public sector could not bear them all. Thus, commercial actors are needed to provide the financial strength to realise some of the hopes and aspirations of the biobank project.

FG4: R1: ...think there must be some other interests [other than govermental] as well to be able to utilise the resources that are there.

A couple of groups rendered HBAS as something different than a pure broker. They thought commercial utilisations of the biobank resources under the regulations and governance set for HUNT and HBAS acceptable, given that the main aim is to develop important products that will improve people's health:

FG6: R1: But as I read it, there are strict guidelines for HBAS ... the projects have to be approved by both the management group [at HUNT] and the REC [research ethic committee] ... there will be specific applications ... I think that it is important use of the material which ultimately should benefit society and individuals ... They can be helped with drugs or new diagnostic tools ... And there are actors in our society that can use this with good intentions, to benefit people and at the same time earn some money.

The focus on useful product development, in addition to financial gain, was seen as crucial, and an important prerequisite to accepting involvement by commercial actors. A further positive factor was that these projects were subject to the same quality controls and ethical evaluations as the traditional academically run research projects. In addition, privacy issues were raised, and keeping the materials and data de-identified or anonymous was seen as an essential requirement for them to be able to perceive these developments as acceptable.

Discussion

Norwegian legislation prohibits "commercial exploitation of research participants, human biological materials and health related information, as such". Based on the assumption that laws actually reflect common morality, we expected to find a strong emotional and moral opposition to commercialisation of biobanks in our focus groups. What we found, however, was a clear distinction between the ethics of donating human biological materials and the ethics of using already donated samples in a biobank. The moral deliberations on organ and blood donations informed the discussions of commercialisation, in the sense that it demarcated them into two different spheres, characterised by two different sets of moral concerns. This can be seen as a strategy to set a boundary between person and things, explained by Hoeyer (2005) as essential to the capitalist market. The *bodily sphere* has to do with our intimate relationship between body and soul, involving strong evaluations on proper and non-proper ways of handing over body parts or biological material to others. The *communal sphere* relates to the communal arena and how we have chosen to organise and carry out activities where there are, in varying degrees, both public and private actors.

The body is not for sale

In our respondents' minds the act of donating human biological material is part of the bodily sphere and needs to be kept outside the realm and the pressures of the market. Being paid for the donation of organs or blood was in general rejected in all our groups, and parallel findings, for example, found by both Schweda and Schicktanz (2009) and Hoeyer (2005). But as indicated in the previous section a couple of the respondents thought that a system where blood donors were reimbursed could be justified while still opposing payment for organs. Our informants first and foremost articulated the threat towards oneself, and being paid would increase the potential for being lured into doing something that in essence could harm. The harm could be divided into two categories. The first would be direct physical harm. The second is the harm towards oneself when human dignity and worth are threatened, or when engaged in actions that lead to fragmentation, objectification and commodification of the human body.

Both of these aspects were drawn upon in our focus group discussions. These intuitions comply with the normative content of various legislation and guidelines. In addition, we can see ideas of the reciprocal principle of gift exchange. As Hoeyer (2005) describes keeping the donation voluntary and free from financial gain the 'gift relationship' puts obligations on the receiver which would be undermined by sale of blood and other body parts. Therefore financial incentives can be seen to distort the essence of the 'donor-recipient relationship' that we as a society has deemed ethically acceptable.

Human biological material should not give rise to *unjust* financial gain

Commercial use of the biobank resource triggered resistance in our groups because of unjust and unfair market mechanisms. This parallels the findings of Haddow et al. (2007) of deep resentment towards the possibilities of private companies harvesting a substantial financial profit. The moral concerns of justice and fairness in commercial use of biobanks were not raised as a problem of unjustness or unfairness towards 'me' as a donor but in more political and communal sense as a problem for 'us'—as part of how we organise our society. It was *unjust* financial gain that was the major problem, not financial gain per se. This is interesting in relation to the restrictive formulated laws and how they should be interpreted.

Ideas about identity and commodification indicating that "something is lost" and people are disrespected when commercialisation enters the picture", as Haddow et al. (2007, p. 278) write, were totally absent in our groups. This

could be due to our discussants clear separation of spheres where they for the most part wanted to keep monetary incentives out of the donor setting. To them it was quite evident that the actual cases of commercial use of the biobank presented had nothing to do with the commercialisation of the body. Despite the aspects of injustice and unfairness, many of our discussants accepted or even endorsed the developments of potential commercial use of the HUNT resources through HBAS. This can be attributed to the pragmatic notion of the necessity of commercial actors' involvement in facilitating the realisation of potential health benefits based on biobank resources also registered by Haddow et al. (2007). The clear distinction made by participants between issues of dignity and justice in these matters questions the emphasis put on human dignity in various expert discussions surrounding the ethical stance of biobank donors.

A recurrent theme in expert discussions is that biobanks contain human biological materials and information that can be seen to embody the donor. As mentioned, we actively facilitated the emersion of these aspects in our focus groups by preceding the discussion on commercial use of biobanks with a discussion of commodification. Contrary to Hoeyer's (2004) findings we did not at any time in our discussions see any expressions of blood or other materials as an elongation of 'themselves' in any particular way. No traces were shown of ideas that blood or other biological materials in the biobank embodied the donors as individuals in a more fundamental manner than that it was a source of information. This is interesting, especially related to the last decade's discussions of genetics and genomics and the essential character it has been given.

The lack of concern for human dignity and worth when talking explicitly about sample utilisation in our focus groups seems to suggest that these aspects primarily are meaningful when biological material is still part of the body. As soon as it is donated a different 'logic' seems to come into operation. Important aspects here can be the generally good standing HUNT has in the local community and the particular framing of HUNT Biosciences. When donors trust the biobank organisation and systems are in place to prevent misuse they do not have to worry, aspects of dignity are taken care of and therefore not discussed. Our findings here parallel the analysis given by Hoeyer (2005); when regulations that by prohibition decommodefy the donor setting are in place we can relax because what is threatening our essence is taken care of. In a biobank setting the deed is done, a gift is given and it is the stewards' responsibilities, not mine, to ensure that anonymity and professional secrecy is granted and that the promises of the project are fulfilled by utilising the resources in a proper manner.

Possible influences of topical framing of the focus group discussions

In the preceding analysis we identified that participants in the focus groups drew a clear distinction between the concern for *dignity* in donation and the concern for *justice* in use of samples. Was, however, this distinction predetermined by the topical framings of our focus group questions? The problems of commercial organ donation were a major concern for the participants when discussing the ethical questions of ‘the market and the human body’, while in the subsequent discussion of HUNT Biosciences the commercial use of blood samples was the matter of concern. Was, in fact, this difference in ethical concerns simply caused by the focus group participants being asked to examine ethical ‘apples and oranges’?

We introduced the first topic of the ‘market and the human body’ in the focus group sessions because conventions and regulations referred to above indicate a link between this theme and the second of ethical problems in commercial utilisation of biobanks. Furthermore, we wanted to give the discussants an opportunity to draw upon their moral reflection on more familiar scenarios of trade and monetary compensation in relation to blood, milk and organ donation when getting into the vaguer area of commercial use of biobanks.

Introducing the topics in this way also parallels the chronology of the endeavour of building large population-based biobanks in Norway. The first step was the primary recruitment of donors and the donation of biological materials and data. Then, when a sufficient amount of donor contributions were processed, the utilisation step—the use of the resources in various research projects—was taken. What commercialisation or commercial use of such biobank resources entails is often unarticulated and unclear. The ethical questions and chronology of this process is thus mimicked in the topical framing of our focus group sessions.

To our surprise, the dignity discourse of the first topic did not at all carry over into the second. Not even the participants who most strongly opposed commercial use of biobank samples referred to dignity aspects in this setting. These participants did not find it relevant to argue from concerns about dignity in the discussion of commercial utilisation of biobanks. Conversely, when discussing the ethical problems of donation of any kind of biological materials the participants framed it in terms of dignity, even when prompted to see it rather as a matter of justice. In our case the topical framing clearly formed the discussions, but rather than giving us a continuum of concerns as indicated by conventions and regulations, a divide of concerns was found.

Benefit sharing and commercial use

For the HUNT donors the general governance of the commercial activities based on the HUNT resources and the benefit sharing implemented in the framework of HBAS was important to be able to accept the developments. We see the HBAS strategy as a viable solution to the ideas of benefit sharing extensively debated and as, for example, called for by Haddow et al. (2007). Though the framework of HBAS (Steinsbekk et al. 2009) lacks the requirement of an explicit proposal for benefit-sharing and an approval of this by a standing committee for each commercial research project as suggested by Haddow et al. (2007), an upfront public contribution fee from each project and financial return to the research and health communities is an essential part of the HBAS strategy. Since biobank activities in essence are collective, the donors’ perceptions of what they had contributed to were to the common good, to future health benefits for the communal ‘us’. The study they had participated in was a government funded, public and collective endeavour. Therefore, it was important to them that the benefits, including financial, should be distributed in what is perceived as fair and just, in a communal manner.

We claim that the insight demonstrated by these respondents can be seen as an understanding of the communal framing of ‘their’ biobank project which does not involve ‘me’ as a single individual. A single donor is not what the project is about; the participation of a single person does not alter the knowledge produced. Or, as Webster et al. (2008, p. 39) registered when talking to lay people about UK Biobank: “For them … one sample did not lead to an analysis or a discovery; rather, it was the group of samples that would provide [the new knowledge]”, thereby acknowledging that what is essentially crucial for the biobank project is ‘me’ as a part of a ‘we’. In the HUNT project this is communicated via its’ public health framing, which has been emphasised from the start. Following this thread it seems appropriate to suggest that the primacy on individual autonomy in biobank settings has been exaggerated. A shift in biobank ethics from the individualistic framing based on traditional medical ethics towards the communal aspects of public health ethics, as argued in regards to bioethics in general by Dawson (2010), also seems to resonate with lay people interviewed.

Commercial uses come in many shapes and forms

Commercial companies and market mechanisms are how we today have chosen to organise essential developments and product delivery both within medical practise and biomedical research. Even though this strategy has negative aspects of exclusivity, potentially unfair revenues and

unequal distribution in many areas alternative strategies do not seem to emerge as viable options. Of importance here is then how commercial companies are regulated when accessing common goods like biobank resources. Equally important is the implementation of proper material transfer agreements, that appropriate benefit sharing mechanisms are in place and the corporate social responsibility strategies within the commercial entities involved. In addition, that the biobank resources are governed in tune with the common project, should be for the common good. Commercialisation per se is not good or bad in the eyes of our participants, but the uses to which it is put are. For or against markets is too simple a question, as our focus groups discussions amply illustrate.

Final remarks

Commercial use of biobank resources is a complex challenge. Is it possible to find an appropriate form in public biobank endeavours? Involving lay persons acquainted with biobanks in a discussion over the ethical implication of a real case of biobank commercialisation gave important insights. The apparent separation of spheres between the act of donating human biological materials and downstream uses of the resources are clarifying. What ‘we’ primarily are afraid of in the arena of human biological material is that the relation between self and body shall be compromised, transforming it into a market relation. Our participants expressed a marked resistance to the idea of ‘selling oneself’. Getting paid is not a morally acceptable solution to the challenge of benefit-sharing. It would only make things worse. Strict policies and regulation of commercial exploitation of human biological material, responds to this deep-rooted moral concern.

This fear, however, is not recognisable when biological samples are stored in the freezers of the biobank. The human biological material is no longer an extension of ‘me’ in the sense that dignity, commodification and self-respect are at stake. For our focus group participants, inherent aspects of unfairness and injustice and ethical aspects of how the market, especially in pharmaceuticals, is run and regulated, became the primary focus when utilisation of the samples was discussed. Although some opposition towards commercial actors was voiced, these intuitions show that it is possible to render commercial use of biobanks ethically acceptable based on frameworks and regulation which hinders commodification of the human body and promotes communal benefit sharing.

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References

- Andrews, L., and D. Nelkin. 2001. *Body bazaar: The market for human tissue in the biotechnology age*. New York: Crown Publications.
- Brice, P. 2009. New funding for UK and Chinese biobanks. *PHG foundation*. <http://www.phgfoundation.org/news/4765/>. Accessed 11 May 2011.
- CGM Riken. 2011. The BioBank Japan project on the implementation of personalized medicine. <http://www.sra.riken.jp/english/project/person/index.html>. Accessed 11 May 2011.
- Cookson, C. 2010. Germany plans mass medical study. *Financial times*, *ft.com*. <http://www.ft.com/cms/s/0/7f7c8190-8793-11df-9f37-00144feabdc0.html#axzz1KdFsze1>. Accessed 26 Apr 2011.
- Council of Europe. 1997. Oviedo convention: Convention on human rights and biomedicine. <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>. Accessed 29 May 2011.
- Council of Europe. 2006. Rec(2006)4 recommendation on research on biological materials of human origin. <https://wcd.coe.int/wcd/ViewDoc.jsp?id=977859>. Accessed 29 May 2011.
- Dawson, A. 2010. The future of bioethics: Three dogmas and a cup of hemlock. *Bioethics* 24(5): 218–225.
- Dinamo. 2011. Edelman trust barometer. Norwegian findings. *Dinamo.no*. http://www.scribd.com/full/47667236?access_key=key-2axeq5u99rj6dxgi9jt8. Accessed 16 June 2011.
- Fugelsnes, E. 2009. Vil hente fram forskningsgullet. [Will retrieve the research gold]. *Forskning.no*. <http://www.forskning.no/artikler/2009/februar/209050>. Accessed 24 Sept 2010.
- Gaskell, G., and H. Gottweis. 2011. Biobanks need publicity. *Nature* 471(7337): 159–160.
- Godard, B., Schmidtke, J., Cassiman, J.-J., and Aymé, S. 2003. Data storage and DNA banking for biomedical research: Informed consent, confidentiality, quality issues, ownership, return of benefits. A professional perspective. *European Journal of Human Genetics: EJHG* 11(Suppl 2): S88–S122.
- Haddow, G., G. Laurie, S. Cunningham-Burley, and K.G. Hunter. 2007. Tackling community concerns about commercialisation and genetic research: A modest interdisciplinary proposal. *Social Science and Medicine* 64(2): 272–282.
- Haines, E. 2002. What can the social sciences contribute to the study of ethics? Theoretical, empirical and substantive considerations. *Bioethics* 16(2): 89–113.
- Hall, S. 2006. £61 m medical experiment begins. *guardian.co.uk*. <http://www.guardian.co.uk/science/2006/aug/22/medicineandhealth.lifeandhealth>. Accessed 11 May 2011.
- Healy, K. 2004. Sacred markets and secular ritual in the organ transplant industry. In *The sociology of the economy*, ed. F. Dobbin, 308–333. New York: Russell Sage Foundation.
- Hoeyer, K. 2004. Ambiguous gifts: public anxiety, informed consent and biobanks. In *Genetic databases. Socio-ethical issues in the collection and use of DNA*, ed. O. Corrigan, and R. Tutton, 97–116. London: Routledge.

- Hoeyer, K. 2005. The role of ethics in commercial genetic research: Notes on the notion of commodification. *Medical Anthropology* 24(1): 45–70.
- Hoeyer, K. 2007. Person, patent and property: A critique of the commodification hypothesis. *BioSocieties* 2(3): 327–348.
- Hoeyer, K., and N. Lynöe. 2006. Motivating donors to genetic research? Anthropological reasons to rethink the role of informed consent. *Medicine, Health Care and Philosophy* 9(1): 13–23.
- Holland, S. 2001. Contested commodities at both ends of life: buying and selling gametes, embryos, and body tissues. *Kennedy Institute of Ethics Journal* 11(3): 263–284.
- HUNT Biosciences. 2011. Homepage HUNT Biosciences. <http://www.huntbiosciences.com/>. Accessed 21 March 2011.
- Irish Council for Bioethics. 2005. Human biological material: Recommendations for collection, use and storage in research. <http://www.bioethics.ie/index.php/human-biological-material-for-research>. Accessed 13 Apr 2011.
- Kass, L. R. 1997. The wisdom of repugnance. *The New Republic* 216(22). http://www.catholiceducation.org/articles/medical_ethics/me0006.html. Accessed 8 June 2011.
- Kettis-Lindblad, A., L. Ring, E. Vibert, and M.G. Hansson. 2006. Genetic research and donation of tissue samples to biobanks. What do potential sample donors in the Swedish general public think? *European Journal of Public Health* 16(4): 433–440.
- Kierulf, P. 2006. Biobank(ing): Thoughts on practical guidelines for collecting material for biomarkers. *Norwegian Journal of Epidemiology* 16(1): 51–52.
- Krueger, R.A. 1998. *Analyzing and reporting focus group results*. Thousand Oaks: SAGE Publication Ltd.
- Kuras, A. 2010. Michigan Biotrust for Health spots opportunities in blood research. *Research Corridor Michigan's URC*. <http://researchcorridor.com/features/michiganneonatalbiobank0003.aspx>. Accessed 11 May 2011.
- Lenk, C., and Beier, K. 2011. Is the commercialisation of human tissue and body material forbidden in the countries of the European Union? *Journal of Medical Ethics*. Online first 22 June 2011. doi:[10.1136/jme.2010.038760](https://doi.org/10.1136/jme.2010.038760).
- Malterud, K. 2003. *Kvalitative metoder i medisinsk forskning [Qualitative methods in medical research]*. Oslo: Universitetsforlaget.
- Ministry of Health and Care Services. 2001. *NOU 2001:19. Biobanker Innhenting, oppbevaring, bruk og destruksjon av human biologisk materiale. [Biobanks. The procurement, storage, use and destruction of human biological material]*. http://www.regjeringen.no/Rpub/NOU/2001/2001/019/PDFA/NOU20012001_0019000DDDPDFA.pdf.
- Ministry of Health and Care Services. 2008. *Act on medical and health research (the Health Research Act)*. <http://www.regjeringen.no/upload/HOD/HRA/Helseforskning/Helseforskningsloven%20-%20ENGELS%20endelig%2029%2006%2009.pdf>.
- Morgan, D. 1993. *Successful focus groups: Advancing the state of the art*, 1st ed. Thousand Oaks: SAGE Publication Ltd.
- Nicol, D., and Critchley, C. 2011. Benefit sharing and biobanking in Australia. *Public understanding of science*. doi:[10.1177/0963662511402425](https://doi.org/10.1177/0963662511402425).
- Nilstun, T., and G. Hermerén. 2006. Human tissue samples and ethics. *Medicine, Health Care and Philosophy* 9(1): 81–86.
- NTNU. 2011a. The Nord-Trøndelag health study. <http://www.ntnu.edu/hunt>. Accessed 25 May 2011.
- NTNU. 2011b. HUNT Biobank. Det medisinske fakultet. <http://www.ntnu.no/hunt/biobank>. Accessed 27 May 2011.
- NTNU. 2011c. HUNT Biosciences AS. <http://www.ntnu.no/hunt/biosciences>. Accessed 4 June 2011.
- NTNU. 2011d. HUNT: En av verdens største helseundersøkelser. [One of the world's largest health studies]. <http://www.ntnu.no/hunt/screening>. Accessed 30 April 2009.
- Palsson, G. 2008. The rise and fall of a biobank. In *Biobanks: governance in comparative perspective*, ed. H. Gottweis, and A.R.P.D. Petersen, 41–55. London: Routledge.
- Policy and Medicine. 2011. NEJM the private sector discoveries account for 79–90% of pharmaceutical products. <http://www.policymed.com/2011/02/nejm-the-private-sector-discoveries-account-for-79-90-of-pharmaceutical-products.html>. Accessed 26 June 2011.
- Research Council of Norway. 2008. *Gode biobanker—Bedre helse. [Good biobanks—Better health]*. Forskningsrådet. Oslo. http://www.forskningsradet.no/en/Home_page/1177315753906.
- Research Council of Norway. 2010. *Potensial for kommersiell utnyttelse av humane biobanker. [The potential for commercial utilisation of human biobanks]*. Forskningsrådet. Oslo. http://www.forskningsradet.no/en/Home_page/1177315753906.
- Roel, J. E. 2011. Bio i banken er gull verdt [Bio in the bank has gold worth]. *Adresseavisen*, March 12th: 14–18. Trondheim, Norway.
- Rose, H. 2006. From Hype to mothballs in four years: Troubles in the development of large-scale DNA biobanks in Europe. *Public Health Genomics* 9(3): 184–189.
- Rothman, S.M., and D.J. Rothman. 2006. The hidden cost of organ sale. *American Journal of Transplantation* 6(7): 1524–1528.
- Schweda, M., and S. Schicktanz. 2009. Public ideas and values concerning the commercialization of organ donation in four European countries. *Social Science and Medicine* 68(6): 1129–1136.
- Seale, C., D. Cavers, and M. Dixon-Woods. 2006. Commodification of body parts: By medicine or by media? *Body and Society* 12(1): 25–42.
- Sharp, L.A. 2000. The commodification of the body and its parts. *Annual Review of Anthropology* 29(1): 287–328.
- Sharp, L.A. 2009. *Bodies, commodities, and biotechnologies: Death, mourning, and scientific desire in the realm of human organ transfer*. New York: Columbia University Press.
- Skolbekken, J.-A., L.Ø. Ursin, B. Solberg, E. Christensen, et al. 2005. Not worth the paper it's written on? Informed consent and biobank research in a Norwegian context. *Critical Public Health* 15: 335–347.
- Stegmayr, B., and K. Asplund. 2002. Informed consent for genetic research on blood stored for more than a decade: a population based study. *BMJ* 325(7365): 634–635.
- Steinsbekk, K.S., B. Solberg, and B.K. Myskja. 2009. From idealism to realism: Commercial ventures in publicly funded biobanks. In *New challenges for biobanks: Ethics, law and governance (GeneBanC project)*, ed. K. Dierickx, and P. Borry, 137–151. Antwerp: Intersentia.
- Taylor, C. 1985. *Philosophical papers: Volume 1, human agency and language (Philosophical papers, Vol 1)*. Cambridge: Cambridge University Press.
- Thomas, C. M. (2006). *A framework for the collection retention and use of human body parts*. Doctoral thesis. Victoria University of Wellington, Wellington, New Zealand. <http://researcharchive.vu.ac.nz/bitstream/handle/10063/297/thesis.pdf?sequence=2>. Accessed 24 June 2011.
- Trinidad, S.B., S.M. Fullerton, J.M. Bares, G.P. Jarvik, et al. 2010. Genomic research and wide data sharing: views of prospective participants. *Genetics in Medicine: Official Journal of the American College of Medical Genetics* 12(8): 486–495.
- Tupasela, A., S. Sihvo, K. Snell, P. Jallinoja, et al. 2010. Attitudes towards biomedical use of tissue sample collections, consent, and biobanks among Finns. *Scandinavian Journal of Public Health* 38(1): 46–52.

- UK Biobank. (2007). *UK biobank ethics and governance framework* (No. 3). UK Biobank. http://www.ukbiobank.ac.uk/docs/EGF_20082.pdf.
- UK Biobank. 2009. UK biobank home page. <http://www.ukbiobank.ac.uk/>.
- Ursin, L.Ø. 2010. Biobank research and the welfare state project: the HUNT—story. *Critical Public Health* 20(4): 453.
- Walsh, F. 2010. DNA bank hits goal of enrolling half a million adults. *BBC News* 7 July 2010. <http://www.bbc.co.uk/news/10544498>. Accessed 26 April 2011.
- Webster, A., Brown, N., Douglas, C., Graham, L., et al. 2008. *Public attitudes to third party access and benefit sharing: Their application to UK Biobank. Final report*. Science and Technology Studies Unit (SATSU) University of York. <http://www.ecukbiobank.org.uk/assets/wtx052208.pdf>.