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The Privacy-Reciprocity Connection in Biobanking: Comparing German with UK Strategies

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Key Words

Biobank · Data sharing · Focus groups · Genetic privacy · Policy · Public engagement · Qualitative research · Reciprocity · Research participation

Abstract

In recent years, the adequacy of the 'gift' model of research participation has been increasingly questioned. This study used focus groups to explore how potential and actual participants of biobanks in the UK and Germany negotiate the relationship between concerns over privacy protection, reciprocity and benefit sharing. In Germany, 15 focus groups (n = 151) were conducted: 11 general public groups (n = 116) and 4 with former cohort study participants including the KORA and the Popgen cohort study (n = 35). In the UK, 9 focus groups (n = 61) were conducted: 4 general public groups (n = 33) and 5 with UK Biobank and European Huntington's Disease (Euro-HD) Registry biorepository participants (n = 28). Forms of reciprocity were found to partially mitigate potential and actual biobank participants' concerns over personal privacy risks and future unintended consequences of biobank in both Germany and the UK. Specifically, notions of individual reciprocity were at the forefront in the context of personal disadvantages to participation, while communal reciprocity was prominent when potential and actual participants were discussing the uncertainty of the long-term nature of biobanking. The research indicates that reciprocity can be viewed as a mode to deal with individuals' concerns about participating in a biobank, both by acting as a return 'favor' or 'gift,' and through establishing an ongoing relationship between participants, researchers and society. It is suggested that future biobanking projects will need to flexibly combine individual and communal forms of reciprocity if they are to recruit and maintain sufficient numbers of participants.

Introduction

When participants are recruited into a biobank study, they typically donate samples such as of blood, urine, saliva, and tissue. These donations are different from giving blood for blood transfusions, where the blood virtually disappears into the large system of blood supply. In the case of biobank research, any sample given to a biobank attains its value by being linked with personal information, such as medical records and social and environmental data [1]. By the very nature of biobank research, then,

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questions of privacy and data protection are hotly debated in an era marked by ubiquitous data collection, new technologies and frequent stories about personal data being leaked, lost or distributed to unintended recipients. Privacy issues raise complex questions for participants' trust, and recent survey data show that people are concerned that their private medical and biological data could be accessed by employers or insurance companies and used in some manner against their interests [2]. Until the last decade, concurrent discussions around the need to offer protection to research participants have largely focused on the role of informed consent. Such debates construct participation and the donation of time, medical information and biological samples as an act of altruism, with 'donated material' construed as a 'gift' involving a free and voluntary transfer with no expectation of return benefit.

However, as economic and commercial views of human tissue have increased, and the line between the body as 'gift' and as 'commodity' has become increasingly flexible [3], the adequacy of these models has been questioned, and concerns about entrenched inequality and the disempowering effects of informed consent have proliferated [4, 5]. Recent discussion has emphasized the need to recognize that when biobank participants 'donate' body substances, they do not just forget about them at some point in time, but rather maintain a complex relationship with their removed, but not completely detached or disentangled, body parts [6–8]. Mary Douglas has famously argued in her foreword to Marcel Mauss' classic *The Gift* that not only are there no 'free gifts' in society, but that to talk about a 'free gift' demonstrates a lack of understanding of the nature of giving, since a free gift that does nothing to enhance solidarity is, in fact, a contradiction [9]. Society is all about establishing mutual ties, an argument developed into a complex social theory by Marcel Mauss and others, such as Alain Caillé [10], who define society as being made up of individuals who constantly attempt to establish their position in society by creating and dissolving bonds with others. This creation of bonds is established through the gifts as a mode of transforming conflict into alliance (and the other way around) through the intermediary of the obligation to give, receive and give back. According to Mauss [9], this bond is 'a tie occurring through things, is one between souls, because the thing itself possesses a soul, is of the soul … to make a gift of something to someone is to make a present of some part of oneself'.

In the context of biobanking, these philosophical and political discussions about the nature of solidarity and society have been reflected in the shift toward conceptions of research donations as 'conditional gifts,' in which participants are understood to attach varying conditions to their donations [11–16]. Such perspectives highlight the ongoing interests of the donor in their donation and emphasize interaction, engagement and collaboration between participants, researchers and society. By focusing on ongoing returns of favors between participants and researchers, this conditional-gift model can incorporate both participants' collective interests in how samples are used or what research is pursued with them, and also their individual conditions of acceptance, and enables participants to retain some degree of control throughout the research process [14].

This process of biobanks 'returning something,' however, is complex and subject to different interpretations and understandings. As such, it then becomes salient to ask what forms of reciprocity or 'favors' are offered to potential biobank participants? One approach that can be observed in biobank-society interactions is to emphasize the public benefits from biobank-related health research and to communicate the potentially significant medical benefits that might manifest at some unspecified point in the future. An example of this is the UK Biobank, which has successfully achieved very high recruitment of a diverse population through general large-scale mobilization by emphasizing altruism and solidarity, and by making a moral appeal for cooperation and assistance to enable a better society in the future [17]. Another approach is to develop a comprehensive system of creating individual returns and benefits for participants in biobank studies, as has been taken by the German KORA (Collaborative Health Research in the Region of Augsburg) cohort study. The KORA approach is also of special interest because it will be emulated in the new German national cohort study, expected to be started in 2013.

Such approaches to reciprocity are not mutually exclusive, and recruitment strategies tend to combine individual and communal notions of reciprocity variously depending on the structure, funding, scope, and research design of the biobank as well as the wider social, economic and cultural contexts in which they are situated [18]. Nonetheless, these differing strategies of recruitment and benefit sharing offer a rich context from which to examine the interaction between privacy and benefit sharing, and the ways in which reciprocity can shape and modulate participants expectations as they navigate the hypothetical risks involved in their participation in a biobank project. They also raise pertinent questions around both the feasibility of upscaling existing small-scale biobanks and the ability of national cohort biorepositories to maintain the long-term cooperation of participants, which is essential to their success.

Based on focus group research with participants of the UK Biobank and the KORA study, together with other biobank participants and wider lay publics in the UK and Germany, we empirically examine how potential and actual participants in population biobanks negotiate the complex relationship between concerns in privacy protection, reciprocity and benefit sharing. We then discuss the broad strategies of recruitment of the UK Biobank and KORA to explore the need for flexible modes of reciprocity in future population biobanking strategies.

Methods

Our research took place as part of a wider, mixed-methods European project into the public perception of biobanks. The overall aim of the investigation was to analyze how people in Europe perceive biobanks and to identify the issues they consider to be of central relevance. For this purpose, we created a comprehensive set of qualitative and quantitative data using focus group and social survey methodologies [19–22]. This article is based on the findings from the focus group research in Germany and the UK.

Focus Group Methodology

Focus groups are a qualitative method of data collection used to study public perceptions, the shaping of opinions and preference structures by drawing on group interaction as well as individual statements on specific topics determined by a moderator [23, 24]. They do not create data about statistical distributions of public opinion and perception, but rather show how and why particular opinions, views and perspectives are shaped in a process of constant interaction with the surrounding social, cultural and political contexts [25]. This allows the researchers to explore the meaning of different phenomena from the actors' own goals, values and points of view, and to understand how publics emerge when faced with a contested topic and negotiate and reconstruct issues in this process [26].

Study Participants and Setting

A purposive, nonrepresentative sampling approach [27] was used to select information-rich cases that represented the characteristics of the anticipated population of population biobank projects in Germany and the UK. In total, 15 focus groups were conducted in Germany (n = 151) and 9 focus groups were conducted in the UK (n = 61). We hypothesized that people who already had experience in biobank studies would have different perceptions from people who had not participated in cohort research, and we were interested in identifying possible differences in order to understand the role of knowledge and understanding in the perception of cohort studies and biobanks. As such, these focus groups were further differentiated in 2 groups, with one set created to mirror the generalized public (lay groups) without any experience with biobank studies, and another set representing people who have already donated blood or tissue or who have previously participated in a biobank study (biobank participant groups).

In the UK, each of the 9 focus groups had between 5 and 8 participants, totaling 61 participants (28 men and 33 women) between the ages of 18 and 99. The focus groups were conducted in West Yorkshire and London. Four focus groups were composed of members of the general public (n = 33). A further 5 focus groups were conducted with people who had participated in biobank studies (n = 28): of which 4 groups contained people who had taken part in the UK Biobank, a population-based biobank (n = 23) and 1 group contained people who had taken part in the European Huntington's Disease (HD) Registry project, a disease-based biobank (n = 5). Participants for the groups with UK Biobank participants and members of the wider public were recruited from the Leeds-Bradford area of West Yorkshire, where one of the UK Biobank assessment centers was located. Recruitment strategies included engaging community partners at the focus group sites to advertise the research, such as community centers, leisure centers and libraries; posting flyers in the targeted areas; advertisements and articles in local newspapers, and an interview with a local community radio station. Potential participants were then allocated into either one of the general public groups, or a UK Biobank participant group, depending on whether they had participated in the UK Biobank. Participants of the UK Biobank were asked to bring their letter of invitation to the group to confirm they had been invited to join the study. All relevant materials clearly indicated that the research was being conducted through the University of York in the UK, in collaboration with the University of Vienna, and not by, or for, the UK Biobank. Participants of the HD Registry project were recruited centrally through the site coordinator for the HD Registry project based at University College London. The focus groups were conducted at local neighborhood facilities, such as community halls. Participants were reimbursed GBP 20 in West Yorkshire and GBP 40 in London as compensation and to cover their travel costs. All participants had to be at least 18 years of age to take part in the study.

In Germany, each of the 15 focus groups had between 9 and 12 participants, totaling 151 participants (73 men and 78 women) between the ages of 18 and 99. The focus groups were conducted in Essen, Berlin, Augsburg, and Kiel. Eleven focus groups were composed of members of the general public (n = 116). A further 4 focus groups were conducted with people who had participated in cohort studies (n = 35): of which 1 group (n = 8) contained people who had taken part in KORA (Collaborative Health Research in the Region of Augsburg), 1 group (n = 8) contained people who had taken part in the Popgen study, and 2 further groups with cohort participants from studies conducted in the Essen (n = 9) and Berlin regions (n = 10). The groups were recruited centrally through recruitment centers located in each of the 4 cities: in Essen through the Institut für Medizinische Informatik, Biometrie und Epidemiologie, Universitätsklinikum Essen; in Berlin through the Robert Koch Institute; in Augsburg through the Helmholtz Zentrum München, and in Kiel through the Studienzentrale Popgen, Universitätsklinikum Schleswig-Holstein. Potential participants were then allocated into either one of the general public groups, or into one of the biobank participant groups, depending on whether they had participated in a biobank study. All relevant materials clearly indicated that the research was being conducted through the University of Vienna. Participants were reimbursed EURO 15 in Augsburg and Kiel, and EURO 30 in Essen and Berlin, in addition to receiving travel costs.

The project received ethical clearance through the Life Science Research Ethics Committee in the Faculty of Social Science at the University of Vienna and was undertaken in collaboration with the Science and Technology Studies Unit in the Department of Sociology at the University of York in the United Kingdom. Written confirmation was received by the UK National Research Ethics Service that the study did not require additional ethical review in the UK by a National Health Service Research Ethics Committee (NHS REC) under the Department of Health Governance Arrangements for NHS REC.

Data Collection

The focus groups were conducted between May and October 2010 in the UK and between April and June 2010 in Germany. Each focus group was conducted by a trained moderator and lasted between 90 and 120 min. To improve national comparability, a common template script was developed which focused on several key socio-ethical issues derived from the vast literature on biobanks. This was pretested on pilot focus groups conducted in Austria and the Netherlands in 2009 and revised based on suggestions by the focus group participants and researchers. The semi-structured script was then tailored to each country with relevant examples and vignettes. Biobanks and the related subtopics were briefly introduced by the moderators at the start of the group sessions. Participants were then asked to discuss possible advantages and disadvantages of biobanks and their willingness to participate or, if they had already taken part in a study, their reasons for so doing. This was followed by the presentation of vignettes to explore the key issues: (1) privacy and data linkage, (2) informed consent, (3) benefit sharing and commercialization, and (4) internationalization. Sessions ended with a discussion of the governance of biobanks. Although the script was structured along several cornerstones, participants were given the opportunity to openly debate and construct their own structures of meaning within the given topics.

Data Analysis

All focus group discussions were transcribed completely in the original language. Transcripts were uploaded into Atlas.ti (v6.2.23), a qualitative data management and analysis software program that facilitates data management, international exchange and control [28]. Structured content analysis was used to ensure comparability of data analysis across countries [29, 30]. The structure of the script provided the categorical framework for a common coding structure, which was then adapted inductively in regular online conferences. To improve inter-coder reliability, researchers in both countries separately coded a selection of English transcripts to ensure they were applying codes comparably. Key passages in the German transcripts were then translated into English by Johannes Starkbaum and reviewed by Herbert Gottweis to ensure accuracy. The content analysis was followed by interpretive analyses to reveal meaning structures and dynamics beyond the manifest level [25]. Relevant phenomena were explored in detail and then contextualized. Microsoft Excel was used to manage the participant information data. Where quotes are used in the results, participants are identified by country ('UK' or 'GER'), the focus group number (1–9 in the UK, 1–15 in Germany) and the group composition (general public or biobank participants). All identifying names and features have been removed from the data to ensure participant confidentiality and anonymity.

Results

All participants completed a participant information form. Demographic information from the focus groups is presented in table 1. Overall, focus group participant characteristics were broadly similar in the UK and Germany in terms of sex, age and employment status; however, there was difference in education level, likely due to the dual nature of the German educational system, in which pupils follow either an academic or vocational route from secondary school onwards.

Privacy and Participation in Biobanks in Perspective: A Matter of Conditions

A key insight from our study is that, overall, there was a great willingness among mixed lay publics to participate in research biobanks in both the UK and Germany. Across both the lay groups and the biobank participant groups in these 2 countries, biobanks were generally perceived to have great potential for society by furthering research into, and treatment of, a wide range of diseases affecting the general population. The main reason for considering taking part or having participated in a biobank study was that it contributed to the 'common good,' typically presented by participants as the progress of medical science or improved population health. However, as we discuss below, in both countries the lay publics' and biobank participants' perspectives toward biobanks were also ambivalent and characterized by uncertainties and doubts about the value and benefits of biobanks. Individuals' willingness to take part was conditional and contingent on an array of contextual factors, with personal privacy risks and the unintended consequences of biobank research, such as discrimination and unethical practices, seen as their greatest concerns.

The Contextual Nature of Privacy

The majority of participants in the focus groups perceived privacy issues as part of a broader setting and as embedded in wider societal developments, rather than as an isolated part of biobank research. Most people expressed distrust in the ability of even the most sophisticated data protection systems to offer complete data protection in the digital age:

> I think we live in a leak society and that's my big worry, that you know, all sorts of systems are supposed to be secure these days and I'm sure to the best of intentions they are, until they aren't. (UK, FG7, UK Biobank Participant)

Table 1. Characteristics of focus group participants

	UK n = 61	Germany n = 151
Gender		
Male	28 (46%)	73 (48%)
Female	33 (54%)	78 (52%)
Age		
Age range	18–99	18–99
Modal age category	61–99	61–99
Highest educational level (ISCED category)*		
0–1 First stage of basic education (e.g. attended compulsory school but no formal qualification)	2 (3.3%)	12 (7.9%)
2 Lower secondary or second stage of basic education (e.g. GCSEs/NVQ level 2 in the UK; Hauptschulabschluss/Realschulabschluss/Mittlere Reife in Germany)	5 (8.2%)	28 (18.5%)
3 (Upper) secondary education (e.g. A-levels/NVQ level 3 in the UK; vocational training in the dual system/Fachhochschulreife/Abitur in Germany)	16 (26.2%)	33 (21.9%)
4 Post-secondary non-tertiary education (e.g. higher education access course in the UK; vocational training in the dual system and Fachschulabschluss in Germany)	0 (0.0%)	29 (19.2%)
5–6 Tertiary education (e.g. Bachelors degree/NVQ levels 4–5/HND/PhD in the UK; Fachhochschule/Universitätsabschluss/Doctorate in Germany)	38 (62.3%)	49 (32.5%)
Employment status**		
Employed	32 (52.5%)	76 (50.3%)
Retired	14 (30.0%)	34 (22.5%)
Student	8 (13.1%)	13 (8.6%)
Unemployed/unpaid work (e.g. caregiver/housework)	7 (11.5%)	20 (13.2%)

* Educational levels are compared through the International Standard Classification of Education [48], using the indicators suggested by Schneider [49, 50].

** Eight participants in Germany did not complete the employment section.

> Today you can hack everything. Whatever is coded with a computer can always be decoded with a computer. It is that simple. (GER, FG15, general public)

However, at the same time, people were accustomed to providing data for various purposes in their daily lives and to some extent were resigned to privacy violations. The boundary between personal and biological data was often blurred in people's explanations, with issues of genetic privacy frequently constructed as just one instance of privacy and people equally or more concerned about access to other personal information, such as lifestyle behaviors or mortgage details [31]. One argument commonly put forward was what we propose calling 'societal privacy-resignation,' in which people regarded the data that they would be giving to a biobank similar to the wealth of information that was already freely or easily available 'out there' anyway, via social media, online shopping, store cards, and so forth, as drew on this as a reason not to be especially concerned. Typical statements that convey this attitude were 'everyone is doing it,' 'data are already everywhere,' 'data is unproblematic,' and 'that's how the world is.'

> It is like with the internet. You couldn't go into the internet [if you were worried about privacy] because you leave traces everywhere. If you go to the DM (supermarket) with your customer card, and then they send you advertisements adapted to your profile, or when you are on the internet, your fingerprint is left, and can be found at any time. (GER, FG15, general public)

> I mean, it's about the use of data and information about me, I probably give away much more information about myself on a weekly basis, doing my shopping, doing stuff online. (UK, FG2, general public)

This was often intermixed with high levels of 'personal privacy-resignation,' in which focus group participants emphasized their thinking that privacy was context dependent, and that although 'younger people,' 'celebrities' or 'criminals' may have to be concerned about their privacy, they perceived their own risk of disadvantage from privacy violation as very low. This was often expressed by comments such as 'I have nothing to hide' and 'I am not important.'

> What's what are they gonna do with it, anyway? You can get my – if you were gonna get my address you could probably get it off like just stealing my mail or seeing something online, and I don't feel like any difference between them knowing that I've got a disease and where I live. I don't see how that's gonna affect me really, unless they've got like a personal vendetta against me or something. (UK, FG1, general public)
>
> If someone was to get hold of it and look at it and say, there's a dark-haired, white, blue-eyed, six-foot-tall, slightly overweight fella, how much damage is it going to do? You know, it's not my credit card details, it's not my mortgage details or anything like that, you know. (UK, FG2, general public)
>
> To hack your banking account data makes a lot of sense, it might involve getting a lot of money, but hacking the databank of a biobank, where is the purpose [and] what exactly can be done with that? (GER, FG15, general public)

Nonetheless, the majority of participants across the focus groups in both countries communicated clear conditions that they would want observed in terms of data linkage. Most important is the desire for regulation and control and the perception that biobanks should take every reasonable step to ensure that third parties, such as insurance companies, police or Government would have limited or no access to the data:

> It must be guaranteed that only hackers can get access to these data. That it is guaranteed that these data are not simply given away. That it does not go the way it did with German Telecom, but that when somebody violates the rules he is really punished, also for the medical doctors. It must be possible to be sure that the data are protected, that they cannot just be accessed by everybody, and that if somebody wants to approach these data he has to go through a lot of work. (GER, FG15, general public)
>
> Yes, I have concerns [about privacy], but when I was reassured that the information was going to be properly managed and secured, then I was okay with it. But if I had any doubt that it might be made available to other parts of the state, I would have thought twice or imposed conditions on my participation on it. (UK, FG3, UK Biobank participant)

The Long-Term Nature of Biobanks and the Uncertainty of the Future

The concerns of focus group participants across Germany and the UK about concerns about privacy and data access were closely connected to their fears about the long-term nature of biobanks and the inevitable uncertainty of the future. Although they were generally willing for their samples to be used for all biomedical research that sought to help people, they were not willing for such information to be used solely for commercial gain or for nonmedical research. People frequently raised concerns about the potential for genetic research to lead to practices that are considered as a threat or as unethical. The 2010 Eurobarometer data show that Germany has the highest level of concern about genetic data in all of Europe [32], and such concerns reflect the social, cultural and political contexts in which people are embedded, with focus group participants in Germany frequently referring to examples of eugenics and medical experiments during World War II. A number of participants also saw the potential use of genetic research by insurance companies as harmful, if they used it to adjust premiums or criteria so as to exclude certain groups of people. Participants from the Ruhrgebiet in Germany were especially concerned about possible exclusions based on illness, reflecting fears about the possible impacts of regional environmental pollution:

> If I take an example: If a disease appears more often somewhere and this get's in the hands of others and they say straight forward – for example an insurance company or health insurance – that they say: not with us, we do not take from this, let's say Essen [City in the German Ruhrgebiet], in Essen there are higher disease rates and the insurance says no, we do not want you from Essen. […] This is of course a big risk. (GER, FG12, general public)

In both countries, people were also concerned that the future eradication of genetic disorders could lead to the devaluing of certain people with disabilities. Others questioned whether it might lead to a narrow focus on genetic health and overly reductionist interpretations of disease, which could increase worries about disease at the cost of well-being and raise unrealistic expectations in society generally. It is often not what biobanks are, but what they might become, that frightens people:

> I think it's a sort of ethical issue about the gathering of this kind of information and what the research may lead to, which is that, when you have to, you have to come up with some analogies here. I suppose, you know, if it becomes possible, firstly to screen out certain kinds of genetic disorder, so that it simply doesn't occur, then great, nobody gets it anymore. But if it simply only becomes possible to identify it, then perhaps those persons and their progeny suddenly become the epsilon minuses [reference to the lowest caste in Aldous Huxley's *Brave New World*] of the future you know, or perhaps they are bred out in some kind of way. (UK, FG2, general public)
>
> Think of the nuclear bomb, for example. The researchers who did the related research never thought that this would be used for

> bombing Hiroshima; they were physicists. And surely, as biobank researcher or user, one needs to think also about the very distant future and the craziest ideas that could be generated by some sick brains. (GER, FG14, KORA participant)

Benefit Sharing and Constructions of Reciprocity

Such concerns over privacy and the future of genomic research have also been reported elsewhere, and are strongly consistent with more generalized apprehension and feeling of loss of control people have towards scientific developments in general [4, 33]. However, it is less clear empirically how potential and actual participants of biobanks in the UK and Germany negotiate the relationship between concerns over privacy protection, reciprocity and benefit sharing. In this study, we found that focus group participants' concerns about taking part in a biobank study were embedded in an underlying framework of mutuality they constructed between the individual and communal or generalized risks and benefits. In this context, different forms of reciprocity seemed to partially mitigate concerns towards privacy and data misuse, both by acting as a return 'favor' or 'gift,' and through establishing an ongoing and long-term relationship between participants, researchers and society.

In both the UK and Germany, focus group participants oriented to their own conceptions and understandings of communal or indirect reciprocity when they were discussing their concerns about the long-term nature of biobanking and the uncertainty of the future. Across both countries people argued that participants should receive feedback about the general outcomes of the studies that were conducted through the biobank, for 3 main reasons: it was seen as a fair gesture; some people expressed interest in the general results from the study, and people liked the idea of seeing what had been achieved with their data.

> Well, I said I would want something back, but it's not, I wouldn't want the financial reward, it's more the kind of, I don't know, it's like when you give blood and you get the little donor weekly magazine through the post and it kind of, it makes you smile every time it comes through because it's such a crap magazine but it's kind of like, a little, 'oh, look what I do,' it's kind of like the child from within coming out sort of thing. (UK, FG4, general public)

> I think that everybody who participates in such a study should have the right to find out the results of this study. What I always notice in this country is that everybody collects something, but what comes out of it I can only find out with great effort, and I think everybody really should have the right to receive a voucher to get this study, and nobody then should come and tell, 'well, you would not understand this study anyhow.' This then means that it would be necessary to write this study in a manner so that everybody can understand it. (GER, FG8, general public)

However, there were also differences between the countries and focus group participants: in the UK, participants emphasized the importance of general feedback and research information to a much greater extent than those in Germany. This was particularly evident in the focus groups with participants of the UK Biobank. In these groups, general research updates were viewed as key to fostering feelings of mutuality and solidarity within the community, which constituted their main reason for participation. Information about who had accessed the resources, and for what purposes, was also perceived as essential to maintaining an ongoing relationship between the participants, researchers and society.

> Another thing that would have been nice to get back is the analysis of what they found from the whole research. I would love to hear, sort of the trends and what they're actually using the findings for at this moment, all that sort of stuff; it would be so interesting to know. (UK, FG3, UK Biobank participant)

> Well then you'd feel that you were doing something that was very worthwhile wouldn't you, you'd think you were part of it, instead of just wondering what's going to happen, even a website we could come on and just see what's happening, to keep us updated. (UK, FG3, UK Biobank participant)

> And I can see an advantage in updates because I think it creates a positive view of things, a positive view while there's so much bad information. You know that here's a group of people working for the human good and you've participated in it, you know. It's uplifting really. (UK, FG8, UK Biobank participant)

For some potential biobank participants in the UK, this was also constructed as the practical intermediary by which participants could retain an element of ongoing control throughout the research process by increasing the transparency of the governance structures and enabling them to exercise their right to withdraw if they considered the biobank to have allowed access to research that they felt was unethical or if they felt commercial interests had taken precedence over the common good:

> Yeah, whilst you want to help medical science and be a part of it, I'm also slightly dubious of what, you know, what your samples are being used for, and you would want to know and it wouldn't, they wouldn't be able to tell you all the time. Maybe just a small amount of control over that would be a good thing. I think if I was to take part in anything like this I'd like to be able to see how the research was actually being used and its effects within society and how it's helping people; that would be quite important for me to get something back. (UK, FG4, general public)

Participants in both the UK and Germany tended to a consensus view on their own accord that resources would be well allocated through continuous web updates, telephone advice lines for those without access to the internet, and opt-in electronic or postal newsletters.

By contrast, individual or direct forms of reciprocity, typically in the form of information about their own health, tended to be prominent when focus group participants in both Germany and the UK were discussing personal disadvantages to participation, such as privacy risks and the time and effort invested in participation, especially where this was on a long-term basis. For the majority of people in the focus groups, the return of some forms of personal health information were seen to act positively as an incentive in the initial conditions of participation, or as a fair exchange for participation, providing that it did not alter the aims of the biobank and unduly use up resources.

> I think it might be more of an incentive for people to use the biobank, if they got certain information back, information about their own health maybe, they might be interested in it, so I think it would be, actually a positive thing to follow the biobanks that do. (UK, FG2, general public)

However, again there were differences between the countries, which were most clearly demonstrated in the difference between people that had participated in a population biobank in either the UK or Germany. In the focus groups with KORA participants in Germany, the return of individual health information or care was constructed as something that participants should expect to get in return for their participation, a 'fair deal', and an incentive to accept data-linkage, since this would enable researchers to provide participants with detailed information about their health. Where this led to regular health checks or treatment that they wouldn't otherwise get, it was also seen to emphasize the collaborative engagement between participant and researcher.

> I think the coding of the medical information is OK. When I have a lung test, and it shows I cannot do 5 liters, but only 2 and 3, and I did not know about this because I don't move much around and I am not very active, then I myself don't notice this health problem. When they say, code number xy has a lung problem, and they identify me, then I want to be notified. (GER, FG5, KORA participant)

> Well, it is all about giving and taking. You are giving information about yourself, about your state of health, in the end intimate details. And in return I want something back. And not just that the general public knows or finds out something, such as that life expectancy is that high in Germany, I myself have nothing from such an insight. (GER, FG1, KORA participant)

> For somebody to participate in such a study it is first of all important to answer the question: how can I profit from participating? What matters is also continuity; on the one hand I get feedback, but that this also then continues. Just as it was with KORA, and I really liked this, that there is another study a few years later building on the original results, and so that I can see developments and tendencies. This is what makes the difference between a good and a bad study for me: continuity and feedback. (GER, FG1, KORA participant)

By contrast, the UK Biobank explicitly states that the assessment is not a health check and that participants' particular test results will not be relayed to them, their General Practitioner (GP) or anyone else [34]. However, in the focus groups, participants of the UK Biobank frequently made reference to the feedback they received as a form of 'health MOT' and a reason for their participation.

> Yeah, but people were coming back from this biobank, I know quite a few that went, and they were all saying the same thing. 'We got a thorough check up for nothing,' and they were delighted with that. You know they're coming back saying 'well, there can't be this wrong with us, we're aware of this now, that we weren't,' and that type of thing. So, in other words, they'd gone and they were happy that they'd got something out it; they've got peace of mind because they knew they had good blood pressure or whatever, so in a way they were getting something out of it, so that made people happier about the situation. (UK, FG5, UK Biobank participant)

> When we actually went, it was an incentive for us to go because it was a bit like a free check-up. You know it was like, you know, getting your blood pressure checked and your blood sugars checked and, you know, a bit of feedback on things that you don't generally just get done for nothing at the doctor's. Or they don't do it as just a matter of course. (UK, FG7, UK Biobank participant)

> Well, I was pleased with it and I'm a bit like, that's one of the incentives for me to go in for I was interested to know how well I was and I was also interested to know about my cholesterol as well because my father had really, really high cholesterol and I've never had mine done, so I thought, 'well, that's a way to find out what mine is.' (UK, FG7, UK Biobank participant)

For the majority of UK Biobank focus group participants, direct feedback of individual health information was only put forward as a boundary issue and not as a condition of participation in a biobank. However, it did lead to significant debate as to what additional health information or care they would have ideally wanted, other than the basic measurements taken in their enrolment visit (i.e. blood pressure, height, weight, estimated amount of fat). About half felt that they would have liked more information back, and often constructed a desire to 'trade' privacy for feedback, perceiving the biobank to hold a duty of care to refer any existing medical conditions they found, either on the day, or at a later date, to their GPs. Similarly to the rhetoric found in the focus groups with KORA participants, the long-term nature of this was also perceived as a manifest sign of the collaborative engagement between participant and researcher.

> The least that we [are] entitled to is information, because it is essentially, it's our information that we're giving to the project. The information actually belongs to us and what we were given

> back is fairly limited. Okay, it's useful to know things like blood pressure, body mass index, percent body fat. I find a lot of information quite reassuring and indeed, even this sparse data that we were given is more than I get in terms of feedback from my MOT visits to my GP practice […] But here [what] they did [was a] much more complicated battery of tests on me and I feel that they know more about my health than probably my GP does. I think it would be an encouragement, an incentive to keep up my commitment to this if each time that I went I was given feedback under those headings and also anything else that can be identified as something that I should talk to my GP about. That's all, information sharing. We're giving them an awful lot more information than they are giving us. (UK, FG3, UK Biobank participant).

> I would have liked to have had a more detailed summary than we actually got. I think there were other things that they could have given and, for example, had there been any major medical problems I think it would have been good if they'd have pointed those out at some stage or other. (UK, FG3, UK Biobank participant)

> In general I think the altruistic thing is fine, but I think one specific thing that should be offered to people as a matter of course would be a follow-up meeting if someone requested it […]. It could be as simple as someone from the biobank arranging an appointment with the GP for that particular individual, sort of facilitating that appointment if the person wanted it. That's the only thing that I think is, well, that's the single most valuable thing that I think that could be offered in return. (UK, FG8, UK Biobank participant)

The Approach German and UK Biobanks Take toward Participants

The two biobank recruitment strategies, the UK Biobank on one hand and KORA on the other hand, reflect two different approaches toward creating reciprocity between a biobank and society. The UK Biobank is a national population resource on the effects of genetic and environmental risk factors of common multifactorial diseases affecting adults in the UK. After a 3-month pilot phase in 2006, it began to collect samples of blood, urine, and saliva, along with physical measures and lifestyle information, from participants across England, Scotland and Wales in 2007. It achieved its recruitment target of 500,000 healthy participants aged between 40 and 69 in July 2010, about 18 months ahead of schedule and within budget [35].

The UK Biobank website and other recruitment materials rely heavily on the language of altruism and solidarity, making a moral appeal for cooperation and assistance to enable a better society in future [17]. The initial invitation letter stated that 'taking part is not intended to help you directly, but it should give future generations a much better chance of living their lives free of diseases that disable and kill' [36]. And the information leaflet continued [34]:

> Taking part in UK Biobank should not cause you any harm. The project aims to observe what happens to participants over the next few decades so that future generations can benefit. It is not intended to change directly what happens to people who take part: in particular, the initial assessment visit is not a 'health check'. Apart from providing you with the results of some standard measurements made during that visit, none of your results will be given to you or your doctors (even if the results do not seem to be normal). This is because such feedback outside of the normal clinical setting is of questionable value, and might even be harmful (for example, causing undue alarm and having potentially adverse effects on insurance status), especially when given without prior counselling or support.

The UK Biobank does not analyze blood, saliva and urine samples immediately following collection. Instead, during follow-up over the next few decades, the stored samples will be analyzed as and when required for approved health-related research. Potential participant's name, address, sex, date of birth, medical number, and general practice were identified from NHS records. Those that were aged between 40–69 received a letter of invitation to join the UK Biobank and attend an assessment at one of 22 centers which were set up during recruitment [37]. Those that accepted provided personal information such as height, weight, blood pressure measurements, details of medical history, and lifestyle information as well as samples of blood, urine and saliva. In consenting to take part, participants granted the UK Biobank access to their full medical records and other records that may be related to health (e.g. occupational or residential information). They were also advised that they might be recontacted by UK Biobank and asked more questions or asked to attend another assessment visit (including questions, measurements and samples), although this was optional. Those that did not want to participate were not pursued. As yet, no participants have been recontacted, but it is intended that a reassessment of the baseline measurements in a sub-sample of participants will be undertaken in 2013.

At the end of the assessment, participants were provided with incidental health information such as blood pressure, pulse rate, height, weight, body fat, vision, fitness, grip strength, bone density, and lung function; representatives from organizations such as the British Heart Foundation were available for people to talk to if they had concerns. Although participants do not receive much in the way of individual reciprocity, there is a strong emphasis on communal reciprocity, and the UK Biobank Participant Resource Centre has been established to keep participants up-to-date with events via a website and by providing a newsletter to participants once a year, sent either by e-mail or by post as requested by the participant. They have also committed to making summaries of approved applications and an indication of their status (e.g. approved/research in progress/completed/published) available on their website. Further, contentious and/or ethically challenging issues related to proposed or approved uses of the resource will be highlighted on the website, in order to allow participants, and the wider public, to provide input on particular research uses and other issues [38].

By contrast, KORA (Collaborative Health Research in the Region of Augsburg) is a research platform based on a population-based cohort study of 18,000 adults from southern Germany, which has been investigating the effects of the interaction between the environment, behavior and genes on health for more than 25 years. The focus of the KORA studies is to survey the development and course of chronic diseases and, in particular, of myocardial infarction, diabetes mellitus and lung disease. Recruitment started in 1984/85 and was performed in 4 surveys (the first 3 within the WHO MONICA project on *Moni*toring of trends and determinants in *Ca*rdiovascular disease), followed by repeated investigations in regular intervals. A random sample of subjects from the general population was drawn from the local registration offices (Einwohnermeldeämter) in Germany. The selected people are then contacted by letter. If they do not respond, they get a second letter and are called by phone, if necessary several times, until contact can be made. The KORA study similarly draws on the rhetoric of the social good, with the website stating that the aim of the project is to 'provide new approaches in the field of chronic disease prevention and enhance public health care' [39]. However, in contrast to the UK Biobank, the recruitment materials aimed specifically at invited participants construct a very different paradigm, based on a model of 'exchange relationship' by which some form of direct reciprocal benefit is to be expected [40]. The FAQs at the KORA Study Center website address the question of benefits available to study participants [41]:

> Q: Are there any personal benefits of physical examinations at the KORA Study Center?
>
> A: If you are invited to come to the KORA Study Center, you will undergo substantial physical examinations. In return, you will get a letter with the diagnostic findings in clearly understandable wording together with the laboratory results, the ECG evaluation, results from ultrasonic testing, and the like. We always do our best to forward them to you as early as possible, and if there are any findings that should be checked with your GP, we will explicitly advise you to do so.

The rationale of this strategy is to ensure a high participation rate and to allow for representative conclusions for the population of interest. If they agree to participate, they provide personal information, details of medical history and lifestyle information as well as samples of blood, urine and saliva. They also undergo a number of physical examinations, such as ultrasound examinations and electrocardiograms. Before they leave the study center, the study physician informs them about any suspicious medical results and asks them to visit their family doctor, if necessary. Within 1–2 weeks after the examinations, the participants get the medical report of the results of their examinations and the results of a small number of routine lab investigations. As a general rule, the participants are not informed about results from later analyses. However, if very relevant health findings are identified later, the study center may ask the ethics committee to decide how they should proceed. Those that do not want to participate are asked to fill out a nonresponder questionnaire to obtain some socio-demographic and medical information. As such, the emphasis in the KORA study is on individual reciprocity, with communal forms much more limited outside of announcements of new activities and important results on local media.

Discussion

The focus group data from Germany and the UK indicates that members of the general public and participants of biobank research do not simply view their interests in their 'donation' as terminating after the initial conditions of acceptance. Rather, their 'conditional gift' [14] was seen to begin what was expected to be an ongoing and long-term mutual exchange of benefits between biobanks, society and the individual. It also showed the central role that establishing such a relationship of reciprocity fulfils as potential and actual participants of biobanks negotiate the relationship between individual and communal risks and benefits, by acting as both a return 'gift' or favor and a means to retain control over the research process. The specific forms that these negotiations took reflect the recruitment strategies of the respective biobanks. Our research indicates that reciprocity can be viewed as a mode to deal with a range of key issues in biobanking, such as privacy and concerns over the long-term future of biobanks, with both lay publics and biobank participants drawing on notions on individual and communal reciprocity as a factor in the terms of participation, and as a means to retain control over the research process by establishing an ongoing and long-term relationship between participants, researchers and society. The majority of participants did not present expectations of data protection as risk-free, rather they argued that no system was 100% secure and gave personal examples from their own experience. However, although participants may be willing to accept the personal risk of loss of privacy, this is not unconditional, but is rather balanced by an exchange of benefits.

The two discussed strategies of recruitment and reciprocity are surely not accidental, but reflect different strategic approaches towards the scope and research design of building biobanks and recruiting participants, and they achieve very different response rates. The fourth KORA survey achieved a response of 67%; by contrast, the response rate of participation in UK Biobank was approximately 10% [35, 42]. It has been argued that low response rates are a minor issue for large cohort studies. For population-based estimates of disease prevalence and incidence, high response rates are required, but this information may be available from nationally representative surveys. On the other hand, prospective cohorts need not to be representative of a population to be generalizable. If a cohort study focusing on disease risk associations has a sufficiently large base population and captures a diversity of exposures and backgrounds, the results can be applicable to populations with different distributions of these exposures. Thus, if the vigor to reach high participation rates is reduced, the costs are considerably limited [35]. However, a different view is also possible. If the response rate is very low, there is a strong self-selection of more health-conscious people; those with more extreme risk profiles will participate at a smaller rate, and disadvantaged groups may not be represented at all, so that diversity may be limited. The resulting cohort has fewer diseases and fall ill later in life, which reduces the incidences and thus the power of the study. Furthermore, the data on prevalence of intermediate phenotypes are often not available from representative studies, and it is not possible to estimate incidences from surveys reliably [42].

However, it is important to also recognize that these contrasting strategies of recruitment were not perceived by participants as mutually exclusive. Participants of the KORA project stressed the need for transparency and the return of general information in order to mitigate the dangers to society from misuse of the information. Participants of the UK Biobank viewed the return of individual health information to them or their GP positively, both as an incentive in the initial conditions of participation, and as a means of emphasizing the collaborative engagement between participant and researcher. This is supported by other studies which have found that most donors to biobanks are interested in getting access to general research results and that whilst participants expectations vary greatly by the setting and context, participants seem always to expect the care they exhibit through donation to be returned in terms of care for their own health where appropriate and feasible [43, 44]. As Kanellopoulou [13] argues, altruism as the only paradigm in biobanking regulation does not anticipate fundamental implications for participants' interests, and it relies on unchallenged assumptions of established trust. Effective mechanisms of control for participants requires an assessment of what appropriate returns would be, a commitment to mutual collaboration and support, and ways of monitoring such collaborations over time.

There is no uniform or ubiquitous model of reciprocity, but it is likely that future population biobanking strategies of participation will need to balance economic restraints against the need to recruit and maintain long-term relationships with sufficient numbers of participants. This raises pertinent questions around both the feasibility of upscaling existing small-scale representative biobanks, which provide direct benefit return to the participants, and the ability of national diverse cohort biorepositories, which rely on their ability to coopt in participants on the basis of a shared solidarity, to maintain the long-term cooperation of participants that is essential to their success. The German National Cohort [45] is currently in the planning stage and aims to investigate determinants of major chronic diseases, their subclinical stages and functional changes (e.g. cardiovascular diseases, cancer, diabetes, neuropsychiatric diseases, and pulmonary and infectious diseases). Special consideration will be given to lifestyle (e.g. physical activity and fitness, diet), psychosocial factors and genetic factors. The research design will be based on the KORA model, and a representative sample of the general population will be drawn from population registries to recruit in total 200,000 men and women aged 20–69 years in 18 study centers across Germany. After 5 years, a follow-up examination will be performed with all participants, supplemented by intermediate postal questionnaire follow-ups every 2–3 years. If the KORA model is to be proven successful at the national level, it is likely it will have to combine the existing strategies of individual reciprocity with stronger emphasis on forms of communal reciprocity that establish an effective ongoing engagement between participants, researchers and society, if people's fears about the potential for data misuse and the long-term uncertainties of biobanks are to be addressed.

As we have sought to show, individual reciprocity serves to incentivize participation and emphasizes the participants' feeling of value to the project and where it leads to ongoing regular health checks or treatment that they wouldn't otherwise get; it was also seen to emphasize the collaborative engagement between participant and researcher. In this context, data linkage and the traceability of samples and data (to provide possibility of individual feedback), and data protection by double coding and/or removal of links to personal identity, may act to rule out each other, and biobanks must make a trade-off between safety measures and reciprocity duties as concerns recontacting individuals. At the same time, such strategies must go in tandem with developing the best possible protection of participants' privacy, since reciprocity concerning privacy risks may also be understood as an obligation on biobanking institutions to protect their samples and data from intrusion by third parties, be it by private insurance companies, employers, police and other state agencies, or by hackers. However, population biobanking strategies must also realize that they have a duty to preserve the 'spirit' of the gift, and that this cannot be done without generating and maintaining a sense of mutuality, solidarity and communality at the national level [31, 46, 47]. Demands for transparency, regular updates and ongoing information on research performed on samples and data are not themselves a benefit, but they are regarded as necessary preconditions to control the conditionality imposed on the biobank in the way that they use their samples, a form of monitoring mechanism to ensure a way to build benefit sharing back to the community and to protect the resource against future unethical practices. In order to meet these multiple concerns, future biobanking strategies will need to be flexible and capable of change, ready to respond to wider cultural shifts in the way in which the body is viewed and able to create new constellations of mutual benefits between research participants, biobanks and society.

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