



Workshop report: Involving publics in biobank research and governance

UK Biobank Ethics and Governance Council

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1 Introduction

UK Biobank is a long-term project to build a major resource of data and samples with the participation of 500,000 individuals from the UK aged 40 to 69 (www.ukbiobank.ac.uk). This resource will support a diverse range of research with the aim of improving the prevention, diagnosis and treatment of illness and promoting health throughout society. At the time the workshop took place 413,000 people had agreed to participate in the project.

UK Biobank operates according to an Ethics and Governance Framework that describes the standards to which the project will operate during the creation, maintenance and use of the resource (www.ukbiobank.ac.uk/ethics/egf.php). The framework also describes UK Biobank's commitment to ongoing engagement with participants and the public. The UK Biobank Ethics and Governance Council (EGC) is an independent advisory body that monitors the project's compliance with this framework and provides advice to UK Biobank on the interests of research participants and the general public (www.egcukbiobank.org.uk). In order to inform itself about these interests the EGC hosts a series of public meetings and has commissioned a public attitude survey on key issues.

The aim of the workshop was to inform the EGC and consequently UK Biobank itself about a number of different methods of public involvement. It was hoped that the outcomes of the workshop would assist the Council by providing evidence for how it might consider the issue of public involvement in terms of its own work and in terms of its advice to UK Biobank.

We present here a report of the workshop, including details of the presentations and the Council's reflections on the day. A background paper is also included to provide further information about UK Biobank and the EGC, including their respective roles and responsibilities in terms of public involvement.

We welcome any comment about this report, about UK Biobank or the EGC's methods of involving publics. Our contact details can be found at Section 7.

2 Agenda

09.30 – 10.00	Tea and coffee	
10.00 – 10.15	Welcome	Graeme Laurie , Chair, UK Biobank Ethics and Governance Council (15 min.)
10.15 – 10.35	Public engagement and the UK Biobank project – a critique	Mairi Levitt , Lancaster University (15 min.) 5 min. discussion
10.35 – 10.55	A participant's view	Ruth Bowles (Study mother) and Katie Creamer (Study young person), The Avon Longitudinal Study of Parents and Children (15 min.) 5 min. discussion
10.55 – 11.25	Consultative Panel – in practice	Cathleen Schulte , Human Genetics Commission Secretariat (10 min.) Paul Myatt , General Medical Council (10 min.) 10 min. discussion
11.25 – 11.50	A Shareholder model – in theory	David Winickoff , University of California (15 min.) 10 min. discussion
11.50 – 12.15	Patient and public involvement in strategic decision-making groups – in practice	Philippa Yeeles , UK Clinical Research Collaboration (15 min.) 10 min. discussion
12.15 – 13.10	Lunch	
13.10 – 13.50	The Citizens' Inquiry and other approaches to engagement – in practice	Peter Mills , Human Genetics Commission Secretariat, and Tom Wakeford , Newcastle University (13-15 min.) Tom Wakeford and Jackie Haq , Newcastle University (10-12 min.) 15 min. discussion
13.50 – 14.20	Reflections on deliberative participatory initiatives – in practice	Celia Davies , Visiting Professor, London School of Economics (20 min.) 10 min. discussion
14.20 – 15.30	Reflections on the day and conclusions	Brief reflections from Panel comprising: Mairi Levitt , Heather Widdows (Ethics and Governance Council member), Andrew Trehearne (UK Biobank), Barry Taylor (Bristol University) and Graeme Laurie (5 min. each) Open discussion chaired by Graeme Laurie to define key conclusions (45 min.)
15.30	Close	

3 Workshop report

The following summary of presentations and key messages is an account of contributions delivered at the workshop and do not necessarily reflect the views of the EGC, UK Biobank or its funders.

Welcome

Graeme Laurie described the purpose of the workshop and defined key terms. The workshop is intended to help the EGC explore a number of general questions such as, ‘What does it mean to involve publics in biobank governance and what role can they play?’ and ‘How can UK Biobank and the EGC involve publics effectively and well?’ In addition, the workshop might help address specific questions such as, ‘Would a participant panel as envisaged in the Ethics and Governance Framework be a good model to implement?’

With a view to addressing the above questions, a range of practitioners has been invited to share their experience of using particular methods of public involvement and to describe the pros and cons of each method. Further, speakers have been asked to reflect on the use of the method in the context of UK Biobank and the Ethics and Governance Council. The aim of the workshop is to consider the desirability of each method and the circumstances in which each method might be applicable.

Public engagement and the UK Biobank project – a critique

Mairi Levitt provided a commentary on the past and present public engagement strategies employed for the UK Biobank project, highlighting three stages of public engagement. First, to design and construct UK Biobank in ways acceptable to the public (and other stakeholders); second, during recruitment, to refine methods of working; and third, to manage the maintenance and use of the data balancing the needs and wants of participants and researchers. She argued that a key question throughout has been how to implement UK Biobank in ways acceptable to the public. This question has been addressed in a range of consultation work (including focus groups, surveys, postal questionnaires, telephone interviews) beginning during the development of the protocol in 2000 and continuing today.

Key messages

Consultations have been conducted with the general public, participants and other stakeholders throughout the development of UK Biobank, demonstrating a level of transparency and openness about the project’s

policies. Arguably, however, the public did not have a say in the direction and flow of the research but were only smoothing its path.

Genetic databases elsewhere use nationalistic rhetoric to appeal to the public, e.g. Generation Scotland promises benefit for ‘Scotland and its people’ and praises the special qualities of Scotland as ‘better placed than perhaps any other country’ for this type of work. The Bristol Avon Longitudinal Study of Parents and Children (ALSPAC) has generated loyalty among participating parents and children, with the active involvement of children from the age of 5 and research findings that are of immediate practical benefit. Arguably it is not so easy for UK Biobank to generate loyalty with fewer contacts with participants than ALSPAC and the lack of a UK identity to which the publicity can appeal.

What purpose will participants’ engagement serve once recruitment is complete and researchers are permitted access? Will this be to affect UK Biobank policy or only to effect it? How will the project’s goal of operating for ‘public benefit’ work in practice? Will publics be involved in decisions regarding what is a public benefit and about the direction of research?

Ultimately, the success of UK Biobank relies on public participation. UK Biobank would do well to trust the public and to use their expertise and experience to shape the future use of the resource.

A participant’s view

The Avon Longitudinal Study of Parents and Children (ALSPAC) participants **Ruth Bowles** (Study mother) and **Katie Creamer** (Study young person) offered their reflections on how the project has involved them over the years and their thoughts regarding the methods and level of involvement and their applicability to UK Biobank.

Ruth introduced ALSPAC, a study which recruited mothers from the County of Avon from the eighth week of pregnancy and has subsequently followed the health of 14,500 children born between April 1991 and December 1992. ALSPAC keeps its participants informed through a variety of means including newsletters, website, local radio and television, text and social networking. The project also involves its participants through discussion groups for young participants, participant membership on the ALSPAC Law and Ethics Committee (of which Ruth is a member) and the Teenage Advisory Panel. Such initiatives have involved participants in the direction of research, in decisions on individual researcher requests, contributing to workshops and consultations, discussions regarding drug company involvement, data protection, data access, consent, feedback and ethical review of studies.

3 Workshop report

Katie described the role of ALSPAC's Teenage Advisory Panel, of which she is a member. The Panel was formed nearly three years ago, meets monthly and has a membership of 20 study young people. The initial aim of the Panel was to retain participant interest in the project but it has evolved to provide advice on all aspects of the project (including interviewing new staff and advising researchers about potential new projects). The Panel is also now represented as full members of the Law and Ethics Committee (of which Katie is a member).

Key messages

[RB] UK Biobank could usefully aim for a personal and local feel to the project in order to successfully involve its participants using similar strategies to ALSPAC. UK Biobank should keep its participants informed about the project's progress and encourage participation in governance. The project will also need to be able to adapt to changing circumstances or requirements.

[RB] UK Biobank should be encouraged to involve participants in the direction of research and to utilise the opportunities in communication technology to involve more people.

[KC] Participants' interests are now more effectively represented due to the work of the Teenage Advisory Panel. As a result of the Panel's advice, the project's newsletters are more relevant to the cohort, the questionnaires are more readable, the focus centre has a less clinical feel, the project is on Facebook and events are held at modern clubs. The Panel has tried to represent a wide range of members and is now seen as an effective group whose advice is regularly sought.

[KC] UK Biobank could usefully establish a similar participant advisory body. While its cohort is much larger than that of ALSPAC it may be worth investigating the possibility of several advisory groups. Further, given that UK Biobank is national, rather than local, it could consider arranging central meetings for its participants.

Consultative Panel – in practice

Cathleen Schulte began by introducing the Human Genetics Commission (HGC), the UK Government's advisory body on new developments in human genetics and how they impact on individuals' lives. One of its key roles is to promote debate and to listen to what the public and stakeholders have to say. The Commission has a Consultative Panel of people who have direct experience of living with genetic conditions and who act as a sounding board for the Commission's reports and recommendations. Cathleen spoke about the experience of working with the Consultative Panel from her perspective as a member of the HGC Secretariat.

She explained that much of the Panel's work is by correspondence, asking for Panel Members' feedback on reports that the Commission is writing, consultations it is responding to or other issues discussed by the Commission. The Commission holds an annual meeting for Panel members and Commissioners.

Key messages

The HGC Consultative Panel was established in December 2001 – the concept was considered innovative and has been copied elsewhere. An independent review of the Commission in 2008, found that more succinct, lay-intelligible and user-friendly communications are a top priority for Panel members.

The benefits of correspondence are that it facilitates participation and Panel members have more time to consider issues than at a meeting. However, due to consultation deadlines it is not always possible to give the Panel a lot of time to respond and there may be other practical issues, such as people changing their email addresses. The benefits of meetings are that they allow more discussion and are more personal while offering an opportunity for exchange and reflecting on other people's views. Conversely, meetings frequently require more resources and not everyone from the Panel can attend (for example due to health, work or carer commitments). It should be considered whether facilitated discussions might promote better involvement of all members.

A Consultative Panel is a valuable mechanism for gaining important insights into the perspectives of those affected by policy decisions and legislation; however, to achieve this requires commitment and time from all parties. An organisation has to be clear about the purpose and committed to the concept of a Consultative Panel. It is important to define where such a Panel fits into an organisation and that feedback to the Panel is meaningful. This can be provided by being clear about how Panel members' views are taken on board and about the final outcomes and policy impact.

In 1999 the General Medical Council (GMC) established a group that later became the Patient and Public Reference Group (PPRG). Initially, PPRG comprised Council members and representatives of patient organisations. In 2006, seven public members were appointed through open competition to provide an independent public perspective. The role of PPRG was reviewed in 2008 and the GMC concluded that its effectiveness was constrained by its role as a standing group with quarterly meetings. Following the review, the GMC decided to establish a Reference Community (RC), comprising 27 members of the public and 28 doctors, appointed through an open process. As a result, PPRG concluded its work at the end of 2008.

Appointments to the new RC took place from March to July 2009. **Paul Myatt**, who manages the RC, spoke about the GMC's experience and decisions regarding the PPRG and about progress with respect to the new RC and its envisaged methods of working.

Key messages

Following their introduction in 2006 members of the public had a very positive impact on the work of the PPRG. However, quarterly meetings were found to be restrictive and the 'Committee style' of involvement was sometimes unhelpful.

The purpose of the new RC is to enable the GMC to access the individual perspectives of a diverse group of members of the public and doctors on a range of issues so as to inform its policy and decision taking. The RC is one way among many by which the GMC works with members of the public and doctors.

Members of the RC are involved through a variety of methods of working, including remote (e-engagement exercises), deliberative (face to face or by phone) and, less frequently, by appointment to boards or working groups.

The pros of the RC relate to flexibility in that it enables the GMC to get a public perspective on key issues when it is needed using a variety of methods (in contrast to the PPRG model). Also, the RC complements rather than duplicates the GMC's continued engagement with representative groups. The possible cons of the RC are that 27 members of the public is a small group and there is a risk over time that public members lose independence by the very process of being involved.

A Shareholder model – in theory

David Winickoff presented his proposal for a shareholder model which seeks to 'move beyond public consultation to embrace participatory forms of resource entitlement'. Specifically, he argued for more direct representation of UK Biobank participants in the project's decision-making and governance processes.¹

Key messages

A major challenge in biobank governance is to strike an appropriate balance between promoting human rights and broader societal values, and promoting conditions for doing cutting-edge science. Participatory governance could potentially help to strike that balance.

UK Biobank participants should have a significant role in Biobank governance. While consultative or advisory groups are necessary, they are not sufficient without some actual share of policy-making power. Practically, actual powers may confer real and perceived legitimacy

to the project and to participatory governance. Ethically, input may not be meaningful or effective without any power of implementation. Without some real measure of legal power, recommendations are often not taken up, or even taken into account. At that point, the input process can backfire, and lose credulity, and may even be worse than no input at all.

Partnership governance would involve the formation of a Participant Association involving all members of UK Biobank's cohort, the election of a Board of Representatives by members of this organisation and the appointment from this Board of a Chair and two Vice-Chairs. While the Board of Representatives would be advisory, the Chair and Vice-Chairs will become voting members on the UK Biobank Board and the EGC respectively. This ensures that a small but real piece of formal power sits with participant representatives.

The structure would not replace other forms of engagement. If a question was controversial, the Board of Representatives might recommend direct input from the Association (e.g. surveys, chat rooms, in-depth interviews, and engagement exercises). But the Board would be an additional trusted body to advise and guide these processes.

The model has both pros and cons: It may be challenging to develop a list of potential candidates for the Board of Representatives and also to hold an election that has meaningful turnout. However, this model gives the participant group, through elected representatives, an actual share in biobank policy-making. This addresses a major criticism of advisory groups and engagement processes. The model translates a vague mandate to involve publics into clear mechanisms that generate participant-informed answers.

Patient and public involvement in strategic decision-making groups – in practice

In September 2006 the Board of the UK Clinical Research Collaboration (UKCRC) agreed to pilot the involvement of patient/public members within some of its advisory groups and subgroups and on the Board itself.

An evaluation of this pilot project was subsequently carried out to assess both the process and the impact of patient and public involvement in UKCRC groups.

Philippa Yeeles presented some of the findings of the evaluation, which were published in January 2009, and also offered an insight into the broader context of UKCRC's patient and public involvement (PPI) activities.

¹ Winickoff, DE. "Partnership in UK Biobank: A third way for genomic property?" *The Journal of Law, Medicine and Ethics*. (2007) 35 (3): 440 – 456.

Key messages

The process and impact evaluation involved review of documents, interviews with PPI members, UKCRC group Chairs and UKCRC staff. Conclusions included that the recruitment process was challenging for PPI members and often excluded people or selected certain kinds of people; there was a lack of clarity about the role of the PPI members (including who they are there to represent); the training, support and administration were seen to be of high quality and the role of the Chair as key to facilitating the maximum involvement of PPI members at the meetings.

Although impacts were difficult to define and assess after only a year of operations, and given the complex social interplay involved at the meetings, the review identified a variety of impacts of PPI membership: Members ask what may appear to be simple questions, but which are actually questions fundamental to the debate, they keep a discussion grounded, they promote issues or questions which members believe would be important to patients and/or the public and they act as a reminder of public/patient accountability. The PPI members often felt they had little impact when Chairs and others felt that their impact was profound.

While many aspects of involving PPI members in UKCRC advisory groups are working well, a number of challenges exist as barriers to achieving an impact. These include the complexity of the context in which patient/public members are operating, the speed at which decisions need to be made and a lack of clarity about the role(s) of patient/public members and PPI membership on the Board (which operates in a particular formulaic way with minimal input from individual members, unlike the subgroups which have substantive work packages and products with which the PPI members can engage).

It is important to the UKCRC to share the lessons which have been learnt during the process of patient and public involvement. UK Biobank is strongly encouraged, in whatever it decides to do, to record it, reflect on it and share it with other organisations.

The Citizens' Inquiry and other approaches to engagement – in practice

The Human Genetics Commission (HGC), in collaboration with the ESRC Genomics Policy and Research Forum and the Policy, Ethics and Life Sciences Research Centre (PEALS) instigated an independent Citizens' Inquiry to consider key social and ethical issues involved in the current and future use of DNA for forensic purposes.

Peter Mills and **Tom Wakeford** spoke from their experience of commissioning and overseeing the Inquiry on behalf of the HGC and its partners.

Key messages from Peter Mills (HGC)

The HGC assembled a group of partners to provide complementary expertise, especially in relation to the design and commissioning of the Inquiry. The expert group of practitioners chosen to carry out the Inquiry, Vis-à-vis Research Consultancy, was asked to establish an advisory group in order to refine the terms of the project specification, while the project itself was overseen by a group comprising members of the HGC, its partner organisations and independent contributors. The relationships between the HGC, its partner organisations, Vis-à-vis and the project group were key to the success of the project, with continuing two-way dialogue being critical to extracting the most value out of the exercise.

An independent evaluation of the process was undertaken at the point when the dialogue sessions came to an end. It found that the model had very effectively engaged and involved participants, both citizens recruited as part of the panels and those who had attended to provide the information, although it was too early at that point to say whether the process had demonstrated to participants that their voices had been heard and that they had contributed to policy development. The model was also found to be effective in creating a space where there could be a genuine exchange of information and critical but constructive outcomes.

The HGC found that the engagement was helped greatly by the presence of some Commissioners at one of the residential weekends. This presented an opportunity for Inquiry participants to put questions directly to Commissioners and to engage in discussion. Participants subsequently attended one of the HGC's quarterly plenary meetings to present and discuss their findings and took part in media briefings to publicise their report. This tried to ensure that the participants' engagement with the issues and with policy makers continued beyond the Inquiry sessions, although following the launch the HGC found it difficult to maintain contact with the Inquiry participants.

As a result of this process the HGC gained: an appreciation of the terms in which DNA is presented in different discourses; an awareness of how opinions develop through exposure to evidence and dialogue; a greater understanding of how to communicate scientific issues to non-specialists; recommendations and evidence for HGC's further deliberations. The Commission's report, 'Nothing to hide, nothing to fear?', was released in November 2009, informed by the findings of the Inquiry and other subsequent consultation work.

Key messages from Tom Wakeford (PEALS, Newcastle University)²

In a departure from conventional public engagement approaches, the Working Group wrote a project specification that made the inclusivity of people from diverse backgrounds a prominent aspect of the process. Given the disproportionate effect the technology was already having on black and ethnic minority communities, efforts were taken to ensure that their voices were sufficiently strong in the discourse. Vis-à-vis Research Consultancy appeared to have thus achieved a respectful and inclusive process for people who were members of some of the most stigmatised communities in the context of the police DNA database.

Our specification for Vis-à-vis included a key aim ensuring that the Inquiry participants' recommendations will have a demonstrable impact on policy. However, given the limited time and resources available it would have been necessary for policy-makers to have been far more involved at an early stage. As is common in such exercises, it was not clear who was responsible for this vital element. Drawing on a grant from the Joseph Rowntree Charitable Trust, PEALS provided additional funding so that a number of Commissioners at the HGC could meet with the Inquiry participants. The participants did not, however, have the opportunity to meet any member of the government. Given the aim of the Inquiry to have a demonstrable impact on policy, this was a problem in the way the Inquiry was conceived.

A process-orientated evaluation was undertaken shortly after the citizens finished their report. Ideally there should also have been a thorough long-term evaluation of the process and its impacts. This is something that PEALS is hoping to do, though resources have not been made available for this.

While many positives came out of the Inquiry, feedback from Vis-à-vis suggests that participants found it challenging that, despite the project specification stating that there would be ongoing involvement with participants, there was a process of disengagement once the deliberation had concluded. There was a sense for some participants that they had been used by the Inquiry process. Although the Inquiry has been cited and quoted widely in various reports the Inquiry members no longer had a mechanism for making their views known in a way that was likely to contribute to wider debates, their opportunity for having a voice having been seen to have passed.

² The presenter asked for it to be noted that this is the perspective of a member of the HGC Working Group, which has been presented without the input of Vis-à-vis, because they required additional resources to attend the workshop above travel expenses, which the EGC was unable to make available.

Although they were not provided with resources to allow it to take place, Vis-à-vis attempted to address this issue by recruiting Inquiry participants through community groups to whom the individual is accountable during and after the Inquiry process and through which participants are able to maintain their involvement in the issue. But with no follow-up funds, and the HGC superseding the Citizens' Inquiry with a more conventional public consultation of their own, the chance for the Inquiry members, or community organisations, to continue the conversation was effectively shut down.

Tom Wakeford and Jackie Haq presented a researchers'/practitioners' review of participatory action research techniques as used in the involvement of people from diverse backgrounds in science and other areas of policy-making. They drew on the work of the Policy, Ethics and Life Sciences Research Centre, which has designed a range of approaches over the last ten years. All of the processes involve the exchange of perspectives on a defined topic between people who are conventionally regarded as experts and those whose expertise has been acquired by experience. Jackie described three co-inquiry projects, the Community x-change Liverpool, Rural Cumbria Community x-change and Stemistry.

Key messages

A key aspect of the deliberative processes is the framing of the topic to be discussed being open to influence by all participants. Rather than restricting themselves to a narrow topic dictated by the funding body, they are able to make recommendations on the issues they think are important.

Issues that have a scientific dimension can be successfully explored through a variety of media including creative writing, drama, cartoons and video.

Common themes of the three projects were the need for in-depth preparatory work, including the involvement of marginalised communities. The co-inquiry projects were deliberative and participatory and valued expertise by experience as well as 'traditional' expertise. The projects involved medium- to long-term involvement and participants want to be heard and to have impact. Trust and credibility are both key to the success of such projects.

Among the major concerns that have emerged is the power imbalance between funders, institutions and participants when it comes to the stage of taking forward the recommendations that are reached.

Reflections on deliberative participatory initiatives – in practice

Celia Davies provided reflections on deliberative participatory initiatives with reference to the day's presentations. She drew on the findings of her book *Citizens at the Centre*, which provides an evaluation of the Citizens Council at the National Institute for Health and Clinical Excellence. The book provides in-depth ethnographic work on citizen participation, including video-recorded observations as well as interviews with all those involved, from the funders and facilitators to the 30 members of the Citizens Council. Celia also spoke from her experience as Director of the Research for Patient Benefit Programme, at the National Institute for Health Research, and her role in supporting and integrating patient and public members of funding committees.

Key messages

Deliberation has a generative potential through which we might gain: a fuller understanding of issues and impact; the possibility of innovative answers; a renewed sense of meaning and purpose among public servants; more confidence, skill and engagement among citizens and a greater legitimacy and solidarity around a 21st-century concept of public services. Deliberation also has a downside in that it is costly, time-consuming, challenging to implement and easily misunderstood and likely to be contested.

When embarking on an initiative like the Citizens Council it is important to understand that traditional ways of working may not work for lay people. Early meetings of the Citizens Council encountered a number of problems, including members being nervous about disagreeing, the discussion being pushed to consensus too quickly and facilitators being good at giving people an opportunity to speak but not encouraging deliberation. Also, experts were outside of their usual comfort zone and faced the challenge of finding new ways to communicate their ideas. There needs to be a transition in thinking from citizen capacity to citizen potential; from using world-class experts to facilitators of adult learning and from facilitation for inclusion to facilitation for dialogue. There also needs to be clarity regarding who the participants of such a body are representing. Are they there in their own capacity or representing a constituency?

From the perspective of supporting deliberative participatory initiatives, one finds oneself engaging and adapting, building new internal resources and keeping abreast of changing concepts of good practice. From the lay experience it is important to avoid drowning in

documentation, instead harnessing both emotional and intellectual energies, experiencing the value of dialogue among a plurality of publics and recognising the importance of mutual affirmation.

When considering ways to involve publics it is important to actively support and elicit citizen potential; to distinguish between involvement in research and involvement in wider organisational governance; to understand and assess the rationales for using individualistic consultative initiatives (panels, reference groups) versus more collective deliberative initiatives. Multiple moments for engagement and multiple mechanisms for engagement are likely to be needed. When involving publics, consider the language you use to describe them (donor, participant etc.), be ready for surprises and be prepared to re-visit issues over time as issues change (for example, as UK Biobank moves from the recruitment to access phase).

Reflections on the day and conclusions

Panel and open discussion chaired by **Graeme Laurie** to define key conclusions.

Key messages

Participants should be given an opportunity to provide input into UK Biobank's agenda and the project should be prepared for the fact that they may not say what we expect them to say. Further, once participants are given this role their input will need to be taken seriously. Whatever method of involvement UK Biobank decides to adopt will need to be appropriate for and reflect the established purposes and objectives of the project. For example, participants have been informed that they will not benefit personally from their participation but instead the benefits are intended for future generations. This altruistic model is not the same as a shareholder model, which is very different in nature. [Mairi Levitt]

Real involvement requires an ability to influence, to be strategic and to have impact on design. If 'engagement' does not have any of these elements then it is really just a form of dissemination and not engagement or involvement or participation. Participation requires more than an 'audience' that receives information. For real engagement to take place some form of 'ownership' or 'power' needs to be built into the mechanism. If engagement is thought to be desirable, then for it to be realisable UK Biobank would need to build participation into the project's governance structures. This should be done in ways whereby the impact of public involvement and participation is transparent and demonstratable. Different models will be more or less suitable for different groups (for example, participants and the public),

in different circumstances and at different times. UK Biobank is a resource to be managed for the public good, arguably making the need for public participation more pressing than in other projects. A useful exercise to undertake in the short term would be to investigate how people define 'public good' and to see how this concept is constructed in different groups. This would inform the development of UK Biobank's access procedures and help the project to create a checklist of public good criteria against which applications for access could be judged. The public good cannot be limited to participants but should instead extend to society. [Heather Widdows]

The particular characteristics of UK Biobank must be taken into account. There is no model for communicating with half a million people across the country over a 30- or 40-year period. UK Biobank needs to set clear communication and involvement objectives and to define achievable goals. It is envisaged that the bulk of the work will be targeted towards keeping people informed about the project's progress but there will undoubtedly be a future need to canvass opinions as issues arise. UK Biobank is moving into a new phase as recruitment is due to end in summer 2010 and the project's communications will evolve accordingly. [Andrew Trehearne]

There is every prospect of developing a shared vision for the next phase of UK Biobank through genuine dialogue and knowledge co-generation. There will be opportunities, not just for dissemination or exchange, but genuinely to find answers to the questions which will no doubt arise as the project enters a new phase. However, there are issues about the mechanism by which to achieve this. There is already some confusion about the role of the EGC and its relationship to UK Biobank in the minds of some people who encounter the two organisations. The creation of a participant panel would create a third layer and potential participants (and others) might be unable to discern the subtle differences between one body and the other. It is important to avoid a proliferation of bodies and, with this in mind, it may be that the EGC will need to evolve over time into a body that incorporates other kinds of voices, perhaps including not only participants and the wider public but also researchers (for example, if a great deal of the future dialogue is going to be about the uses of UK Biobank data and samples). Finally, it might be advisable to invite the public to discuss some of these issues – how does the public feel they can best be involved with the project? [Barry Taylor]

UK Biobank's communication focus has chiefly been on informing people about what taking part involves. Now that the project is transitioning to a phase where researchers will start to use the resource, it is an

appropriate time to consider a change of emphasis. But canvassing a range of views and input does not necessarily mean that obvious solutions emerge. Indeed, quite the opposite can be true. Different people may well be concerned about different aspects of the use of the UK Biobank resource. So, even if an apparently "representative" panel of participants was established, it is not likely that it would fully reflect the particular concerns of particular individuals. Instead, bearing in mind the scale of the study and its national distribution, we need to be more imaginative in the ways that we use new technologies to allow a wider range of individuals to comment on the ways in which the resource is used. Some uses may raise issues that concern one group of individuals, while other uses may raise issues that concern other groups. With the website – 60-70% of participants indicate that they have access – supplemented by more standard approaches where necessary, it may be possible to engage a much larger proportion of participants in discussions about the issues that concern them. UK Biobank is an experiment on a scale that has not been undertaken before. We should aim to be inclusive, not tokenistic, in our approach to communication and involvement. [Rory Collins]

Useful points coming out of the presentations and the discussion:

What does UK Biobank and the EGC want to achieve by involving participants or the public and how would such activities add value? What are people's expectations of involvement? Moving forward to the access phase there may be an opportunity for public involvement in shaping and directing how the resource is used.

ALSPAC has demonstrated a successful model for achieving two-way communication between participants and the project. The challenge for UK Biobank would be how to translate the success of local project's participatory engagement processes to a national project.

Researchers and the proposals that they submit will largely determine the use of the resource; the scientists building UK Biobank will have no preferential access. UK Biobank has been focusing its communications on raising awareness about the project and has endeavoured not to raise people's expectations about involvement. At the access stage UK Biobank will need to adopt different methods of communication in order to inform participants about how the resource is being used, and from an engagement perspective, new approaches will be needed if participants are to be given an opportunity to comment and to see their comments being taken seriously. On the latter point, UK Biobank will need a strategy to explain why comments are not being acted on, if this is the case.

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A UK Biobank deliberative participatory group might be used in two particular ways during the access phase:

- To re-present to all participants the purpose and potential of the studies using UK Biobank in a language that is accessible and meaningful.
- To engage in agenda-setting by commenting on potential research projects and inputting to access decision-making. This way UK Biobank might be able to say that it is a resource for the scientific community but also a resource for participants. What is at the top of people's minds? How would they like to see the resource being used (this may or may not be different to how researchers are proposing to use the resource)? Does anyone know the answer to these questions? If not, then UK Biobank and its funders are in a position to find out.

Agenda setting is largely the domain of the organisations that will fund future research, for example Research Councils like the MRC and funding bodies like the Wellcome Trust. Building alliances between funding agencies and biobank participants would be one way of working towards more inclusive research agenda-setting. This is different to involving participants in governance, for example in shaping issues around access and use, which is very important and immediate for UK Biobank and which will require different strategies.

There is an imperative to move away from polarised thinking that there is a pro-science and an anti-science view in society (for example, as in the GM debate). More valuable is a commitment to genuine communication and engagement and, where appropriate, involvement in decision-making and agenda-setting. While this is probably easier in a smaller scale, there is a danger that if robust and appropriate methods are not deployed on a large-scale, as with UK Biobank, there could be a backlash and a return to polarisation when this is entirely avoidable.

Different groups understandably have their own agenda and ways of seeing the world. For example, the doctors on the GMC's Reference Community are likely to have a more homogenous view as a group, and have more in common, than the group of public representatives. This raises its own challenges but these are not insurmountable. The GMC works separately with the doctors and public representatives on some issues to ensure that the voices of each group are heard.

The stakeholder model seems to suggest that participants should have more say or more opportunity to influence UK Biobank than members of the general public, implying that this is a reward (or reciprocity) for participation. This is questionable not least given that the opportunity to participate in UK Biobank is limited

by age and geographical location and that UK Biobank is a resource for the entire public good. If participants are asked to be involved in agenda-setting, who would benefit from this exercise – participants, UK Biobank or the public good? Again, is this akin to a reward for being a participant? Could it become tokenistic? Moreover, does this appropriately reflect the purpose of UK Biobank? Some examples given at the workshop related to organisations that provide a service (for example, the NHS) where an individual could suffer if those services are not provided adequately and therefore where their input is in some sense self-interested. However, UK Biobank is not providing a service and therefore certain models of involvement will not be appropriate. Before consulting with participants and the public we have to ask what purpose will be served and what difference it will make.

The counter-view to the above was also expressed: the public should indeed be consulted but for participants who give pieces of their body and their time and contribute more than taxpayer money there is a new ethical plane that arguably requires them to be involved and have some real power in relation to the project's use and development.

UK Biobank's recruitment phase is a tremendous success story and will result in an enormous resource that can be used in a variety of ways for the public good. But how can you get a public voice into the governance? The reality and the challenge for UK Biobank is that there are a variety of voices which can be raised to have a say at this juncture and at future milestones in the project. It is clear that no one-size-fits-all model emerges as relevant or appropriate to UK Biobank. Nonetheless, many lessons might be learned from the experiences of others who have undertaken public engagement exercises.

4 EGC reflections on the workshop

4.1 Introductory remarks

In order to provide a context for its reflections the Council considers it important to make a few introductory remarks:

- UK Biobank and the EGC have distinct roles and responsibilities in terms of involving the public and participants. In making its recommendations the Council aims to distinguish between how UK Biobank might address the question of involvement and how the EGC itself might address the question. It should also be reiterated that none of the views expressed above should be taken to reflect the views of the Council, UK Biobank or its funders. The Council is most grateful to participants and presenters at the workshop for sharing their experiences and insights.
- When offering recommendations it is useful to distinguish between:
 - methods of communication and transparency (e.g. newsletters, website)
 - methods of public and participant engagement (e.g. public meetings)
 - methods of public and participant involvement (e.g. consultative panels).

4.2 General conclusions

- There can be good reasons for undertaking public involvement initiatives and such activities have clearly gained in popularity in recent years. However, tokenism should be avoided and there need to be clear benefits and public interest reasons for carrying out such initiatives. Any initiative must be judged in its own context and in this report the context is UK Biobank.
- In the UK Biobank context public involvement could serve a number of purposes, for example to give people a voice and for both UK Biobank and the EGC to receive input into their respective decision-making processes. For UK Biobank this could serve as a means to keep participants involved and engaged and so promote the success of the project by mitigating the possibility of people withdrawing; to manage risk. For the EGC robust public engagement could help to improve its communication activities and allow it to be more responsive to public and participants expectations of the project.
- The Council does not find that there is one single model which is appropriate or suitable for UK Biobank or itself. Different methods of communication, engagement and involvement will be required at different stages of the UK Biobank project. These are not necessarily mutually exclusive. Notwithstanding, each strategy at each stage must be appropriate to

reflect the project at that time and the needs and expectations of participants and the wider public:

- During set-up and recruitment, UK Biobank may focus on public consultation on specific issues as and when required, for example concerning the development of access procedures. Once a cohort has been established, however, the project might need longer-term participant involvement in a more structured and formal way.
- Over time UK Biobank will face issues of different sensitivities among participants and indeed wider society; addressing these will require UK Biobank to take different approaches. For example, some issues could be considered by a participant panel only, whereas UK Biobank might consult the whole cohort on more contentious matters (e.g. a particular research use).
- UK Biobank has obligations to both its participants and members of the public. Different methods might be more or less appropriate for these different groups (for example, representation on the Board or EGC might be appropriate for participants whereas citizens' inquiries might be used to involve the broader public).
- Regarding communication, UK Biobank will need to employ a variety of methods over time if sections of the community are not to be excluded.
- There will be certain limitations that arise out of the nature of the UK Biobank project. For example, involvement methods successfully employed on a local scale will not extrapolate to a national project like UK Biobank. It does not follow, however, that lessons cannot be learned from those local experiences, nor that local engagement around the UK could not feed into central UK Biobank policy.
- Transaction costs need to be considered carefully. That is, both the economic cost and the cost in terms of time and commitment for all concerned must be weighed in the balance. This re-emphasises the crucial importance of being absolutely clear what a public strategy is designed to achieve and how best its objectives can be met.
- Public engagement and involvement should not be used only to smooth a path towards a previously agreed and fixed end-point. Where deployed, these initiatives should be used to inform and potentially impact upon the strategic direction and use of UK Biobank. For example, prior to the launch of UK Biobank the public was consulted on how the project might be governed to promote public trust. Looking to the future it will be important for participants and the public to be able to express a view and potentially influence how the resource is used.

4 EGC reflections on the workshop

- Where involvement methods are employed participants should ideally have the opportunity to influence policy or decision-making or, at least, have their views taken into account. Clear communication strategies are required to convey this, especially when particular views do not have the result of changing particular policies or decisions. Explanations and justifications of particular policy decisions should be an integral part of UK Biobank's communications strategy.

4.3 Opportunities and threats

In this section we consider the practical potential of public involvement mechanisms (i.e., communication, engagement and direct involvement) in relation to three distinct issues. These issues have been chosen from recent experiences of the EGC in its dealings with UK Biobank. This account includes an assessment of both the likely opportunities and threats associated with UK Biobank conducting, or foregoing, involvement.

4.3.1 Cloning

In recent years the Council has received a number of questions from members of the public about the potential for UK Biobank samples to be used for research involving the cloning of human admixed embryos.

The EGF states that UK Biobank will not proscribe any medical or other health-related research uses at the outset but that approval will only be given to uses that fall within the project's purpose. This purpose is 'to set up a resource that will support a diverse range of health-related research intended to improve the prevention, diagnosis and treatment of illness and the promotion of health throughout society'. Further, the EGF states that UK Biobank will act in accordance with all relevant legislation and that any research use must be scientifically and ethically approved. The creation and use of human embryos and human admixed embryos can only be approved under licence from the Human Fertilisation and Embryology Authority (HFEA). It is a criminal offence to act without a licence. UK Biobank could not therefore grant access for embryo-related research without HFEA approval and this approval would not be given if there were not sound scientific and ethical reasons for the research. Thus, any application for such a use would be vetted to be sure that the use was scientifically and ethically approved, was permitted by law and fitted the purpose of UK Biobank.

The model of 'broad consent' adopted by UK Biobank, which can encompass a wide range of future uses of the resource, requires important, complementary obligations on behalf of the researchers. These are, namely, but not exclusively, that: participants will be kept informed of the research being conducted on the resource (for example, via newsletters on the project's website) and, importantly,

participants can withdraw at any time (for example, if they become unhappy with any particular use). Crucially, research must be judged to be within the stated aims of UK Biobank and in the public interest.

The creation of embryos has never arisen as a potential use of the resource during the Council's discussions with UK Biobank. Should this become a possibility in the future, however, the Council would direct its attention to the issue and might consider a recommendation to UK Biobank to survey the opinions of its participants and the public before any such access request were considered. While it is clear that there is a strong public interest in scientifically sound health-related research, UK Biobank must also take account of other public interests that may be at stake such as (lack of) public support for controversial uses of the resource. If this is not done UK Biobank may face the threat of participant withdrawals if uses of the resource are found to diverge with the public's prevailing interest. Conversely, active involvement of participants and the public offers UK Biobank the opportunity to make participant and public-informed access decisions and to carry the project forward in a way underpinned and supported by the public and participant opinion (as it may change over time).

4.3.2 Re-contact

Participants consent to the possibility of being re-contacted by UK Biobank at some indeterminate future time (for example, to answer some more questions and/or attend another assessment visit). To date the project has primarily re-contacted participants to ask them about their assessment centre experience in order to learn from these experiences and to make improvements to the recruitment process. At the time of writing the project is preparing to re-contact and survey some participants to assess their understanding of their future involvement with the project. This postal survey may lead to telephone interviews and focus group work to discuss issues such as the frequency of re-contact.

Very different views have been expressed at the Council's public meetings about what might be an acceptable frequency of re-contact; some regarded two approaches per year to be too frequent while others regarded five per year as acceptable. Therefore, while involving participants in the development of the project's processes presents an opportunity to learn from past successes and challenges it may also present a threat in terms of re-contact fatigue for some participants (and their possible withdrawal). Public expectation of involvement in research has changed over recent years. It will be essential for UK Biobank to monitor these expectations as they are likely to change over time and as the project matures. While UK Biobank needs a re-contact mechanism in

order to survey its participants about their interests and expectations as well as for research-related approaches, it will need to be mindful not only of this opportunity but also the associated threat.

4.3.3 Broader equality issues

UK Biobank aims to be generalisable rather than representative of the UK population so that research using the resource may benefit a wide diversity of people both nationally and internationally. While the phrase 'representative' was used during the early stages of the project, the incongruity of the phrase is illustrated by the process of recruitment. For example, given that individuals voluntarily respond to UK Biobank's invitation to participate in the study, the cohort will not be representative of the UK population, but of those willing to participate. Further, only certain individuals who are aged 40 to 69 at the time of enrolment and who live within one of the limited number of geographical locations are invited to participate.

In terms of minority groups, such groups would need to be over-recruited to a very substantial extent in order to provide scientifically meaningful numbers of individuals. The Council understands that UK Biobank does not intend to do this but instead that collaboration with other studies will be key – including, for example, studies taking place in China, India and Mexico – where specific ethnic groups are the majority, not the minority.

Notwithstanding, the Council considers it important that everyone who is invited by UK Biobank should have an equal opportunity to participate. This may require specific strategies and methods of engagement for those groups known to be more unlikely to participate in research, or less likely to be reached through standard awareness-raising techniques. While acknowledging that UK Biobank does not intend to over-represent certain groups in order to provide scientifically meaningful numbers, the Council considers it important from a prudential, political and ethical viewpoint that UK Biobank aims to be as inclusive as possible. A potential threat of a non-inclusive process of engagement and involvement would be the criticism that the project will not benefit all communities to the same extent because the collected data and samples relate to the health issues of only a proportion of the UK population. The opportunity is for UK Biobank to establish best practice for being as inclusive as possible of all those invited to participate and to evidence how it has met its commitments to recruit a widely generalisable population sample as is practicable. This also has implications for access policies and decisions with respect to the resource.

UK Biobank has addressed the recruitment issue through the placement of its assessment centres in locations with diverse groups of people. Also, the project

has undertaken a communications campaign at the launch of each new assessment centre involving local groups and community leaders, including providing information to faith and health groups, disability networks and to British Black and Asian community groups and leaders in addition to advertising on British Asian and Punjabi radio. The Council acknowledges and gives credit to these efforts and has recommended that UK Biobank demonstrates further serious attempts to overcome barriers and to engage and facilitate participation for all groups during the final stages of recruitment. Looking to the future, there may be merit in the project enhancing the social data collected from each participant in order to help researchers investigate in more detail the social determinants of health.

4.4 Specific conclusions with respect to particular methods of involvement

This section contains the Council's conclusions with respect to the particular methods of involvement that were addressed during the workshop. A pros and cons approach has been adopted and we point to issues for further consideration.

CONSULTATIVE PANEL

A 100-person consultative panel, akin to that of the Human Genetics Commission's (HGC) Panel, could be a useful mechanism through which a variety of opinions and perspectives are brought to bear on UK Biobank's decision-making processes and policies. Such a panel would most appropriately be convened and managed by UK Biobank (rather than by the EGC) as a means of direct engagement with some of its participants. The General Medical Council model of 27 members of the public and 28 doctors might also be useful in that this smaller group could receive training and support to develop their independent voice. However, the EGC found a larger Panel, such as the HGC model, to be potentially more useful.

Pros

- This model provides a group of informed people to act as a sounding board, and advisors, to UK Biobank.
- The Panel could operate remotely by electronic communications, inputting advice to UK Biobank as and when necessary (rather than meeting at fixed points in the year).
- The use of electronic communications might reduce the cost of the Panel, although an annual face-to-face meeting would be a useful way to keep Panel members engaged (with the project and each other).

4 EGC reflections on the workshop

Cons

- Such a Panel would not be representative of the UK Biobank cohort.
- Panel members may lose their independence over time by the very process of being involved.
- It would be both costly and time-consuming to establish an effective Panel with the necessary support in the long term.

Other considerations:

- In order to make the Panel as effective as possible sufficient time would need to be given to:
 - communicating the purpose and context of the Panel to its members.
 - providing an explanation of how the decisions of the Panel are taken on board by UK Biobank (including an explanation of why recommendation have not been acted upon, if this is the case).
 - developing a pathway from the Panel to the Board and the EGC so that its opinions and concerns are explored.

A SHAREHOLDER MODEL

The Council considered this to be an interesting model but one that focused too greatly on participants rather than the public more broadly.

Pros

- The model encompasses an independent, democratic process to elect participant-members of the Board and the EGC (rather than individuals being selected by UK Biobank or the funders).
- It provides a method for embedding a participant representative at the heart of the decision-making process with formal power.

Cons

- To construe participants as 'shareholders' is to suggest that they should expect, or are owed, some kind of return for their participation. This goes against the 'public good' nature of UK Biobank and against the message that participants are not the intended beneficiaries of research conducted on the resource; the benefits are intended for future generations.
- The proposed process for establishing and maintaining a participant's Association was considered by the Council to be potentially impractical due to cost and administrative complexity.

- Given that the proposal involves only a few individuals to sit on the Board and EGC, members also saw this model as potentially only allowing a few strong voices to be heard.

PATIENT AND PUBLIC INVOLVEMENT IN STRATEGIC DECISION-MAKING GROUPS

There were mixed opinions on the Council as to the potential value of participant involvement on the Board and the EGC.

Pros

- This method embeds a participant representative at the heart of the decision-making process on the Board and/or the EGC.
- This method potentially allows persons from a wide range of backgrounds to participate in governance mechanisms.
- This method provides direct input 'from the perspective of' the participant.

Cons

- It provides an opportunity for only a limited number of people to express their views and which are not in any meaningful sense 'representative' of the wider cohort.
- The required administrative support of the participant-members might be costly and time-consuming if they are expected to communicate with or be available to the wider cohort.
- This method might privilege the participant perspective over wider considerations about the resource as a public good.

THE CITIZENS' INQUIRY AND OTHER APPROACHES TO ENGAGEMENT

The Council considered that there might be real merit in using deliberative participatory initiatives for specific issues as and when necessary. Such initiatives could be equally useful to UK Biobank and the EGC in the fulfilment of their respective responsibilities.

Pros

- Formal methods for facilitating deliberation on specific topics, as and when required.
- Different initiatives could involve different people, giving more people an opportunity to be involved and mitigating the possibility, as found with a Participant Panel, of a loss of independence over time.
- This approach avoids the problem of seeking 'representativeness'.

Cons

- Initiatives are likely to be costly and time-consuming.

Other considerations

- It could be valuable to conduct pilots on this approach in the first instance. For example, the Council can see considerable merit in conducting a Citizens' Inquiry during the development of UK Biobank's Access and Intellectual Property procedures.

4.5 Recommendations to UK Biobank

UK Biobank's Ethics and Governance Framework contains a clear commitment to maintaining ongoing engagement with participants and the public. Accordingly, the Framework describes that the project will develop ways for communicating with, and listening to, participants, the general public, research users and the scientific community. As affirmed in its April 2010 funding renewal application, UK Biobank will send newsletter updates to its participants and will arrange national and/or regional public meetings at which topics of interest can be discussed. Participant feedback will be important in terms of how the resource is being used and its future development. UK Biobank has indicated that one strategy for garnering views on particular issues might be to engage virtual participant panels acting via the project's website. All of these efforts are welcomed as part of a wide and ongoing engagement strategy throughout the life of the project.

The EGC does not consider that it is its role to recommend to UK Biobank any particular outcome or approach with respect to public involvement exercises. The purpose of this workshop was to garner evidence about the methods available and to understand better how these might apply to UK Biobank. As stated above, it is likely that a variety of approaches will be relevant to UK Biobank and its relationship with participants and society over time. The Council finds merit in some of these approaches but all depends on context. The EGC strongly urges UK Biobank and its funders to consider the opportunities and threats of public involvement carefully and closely both now and into the future.

5 Biographies

Ruth Bowles is a study mother and currently vice-chair of the Avon Longitudinal Study of Parents and Children (ALSPAC) Law and Ethics Committee. She is a registered nurse by profession, specialising in intensive care work and has many years experience as a Sister in the Cardiac Intensive Care and High Dependency Unit at the Bristol Heart Institute, contributing to the nursing and medical research that is undertaken there.

Matt Brown, Centre for Longitudinal Studies, is the survey manager for the National Child Development Study and the 1970 British Cohort Study. Matt was previously employed by BMRB Social Research and has an MSc in Social Research Methods.

Rory Collins is UK Biobank Principal Investigator and Chief Executive. He is co-director of the University of Oxford's Clinical Trial Service Unit and Epidemiological Studies Unit and Professor of Medicine and Epidemiology at Oxford, supported by the British Heart Foundation.

Katie Creamer is a participant of the Avon Longitudinal Study of Parents and Children (ALSPAC) and member of its Teenage Advisory Panel and Law and Ethics Committee. Currently studying A Levels at Redland Green School in Bristol, Katie hopes to study medicine at university next year.

Sarah Cunningham-Burley, Professor of Medical and Family Sociology, University of Edinburgh, is Head of Community Health Sciences and Co-Director, Centre for Research on Families and Relationships. Her research interests cover a range of health and family-related issues, including the context and impact of genetic and other health-related developments in medical science. She is also a member of the Human Genetics Commission, where she is lead member of the databases monitoring group.

Celia Davies is Professor Emerita at The Open University and Director of the Research for Patient Benefit Programme in the National Institute for Health Research. She is a sociologist who has published on health professions, health policy and the organisation of health care. Making space for absent voices in public policy was an interest she developed as Professor of Women's Studies at the University of Ulster in the 1980s. *Citizens at the Centre* (with M Wetherall and E Barnett) was published in 2006.

Jackie Haq MBE is Co-Inquiry Research Associate at PEALS (Policy, Ethics and Life Sciences) Research Centre at Newcastle University, where she is developing a critical, sociological analysis of public engagement with science, with a particular focus on the co-production of knowledge through respectful, participatory processes. Her research explores the roles, dynamics and understandings of diverse communities, academics, scientists and policy-makers involved in interrogating science in society today. Her work is firmly grounded in over two decades of collective action within communities delivering pragmatic and strategic responses to urban decline and regeneration. Dr Haq has contributed to policy development locally, regionally and nationally: she is currently a Director of Trafford Hall (National Communities Resource Centre) and is a member of the Synthetic Biology Public Dialogue Oversight Group.

Jonathan Hewitt, EGC member, is a consultant Geriatrician for Portsmouth NHS Trust where he leads a team responsible for a large acute geriatric ward. He is a trained epidemiologist whose PhD investigated the prevalence and complications associated with diabetes in a large group of community-based people aged 75 and over. He has written a number of peer-reviewed papers and a book.

Stephen Howse worked as a senior IT manager with Board responsibilities for major public companies and ran his own IT consultancy business before retiring early due to Beckers Muscular Dystrophy. He is a governor for two schools and has main Board and five subsidiary Board memberships for Regenda, a registered social landlord and charity.

Roger Higgs, EGC member, is Professor Emeritus and former deputy head of division at GKT School of Medicine, King's College, London. He retired from the Department of General Practice and Primary Care at King's at the end of July 2004, and until March that year worked as a general medical practitioner within the inner-city practice that he founded in 1975.

Ian Hughes, EGC member, is a Professor of Pharmacology in the Faculty of Biological Sciences, University of Leeds. He is Chair of Leeds Partnerships NHS Foundation Trust and has held non-executive Director appointments in the NHS since 1986. His research has focused on both the scientific and educational aspects of pharmacology and he has published over 70 refereed papers.

Adrienne Hunt, Secretary of the EGC, is responsible for the executive and administrative support of the Council. Trained as a biochemist, she spent several years working on the Human Genome Project. More recently, she worked in academia, undertaking research on the ethical issues raised in the context of public health interventions.

Graeme Laurie, Chair of the EGC, is Professor of Medical Jurisprudence at the University of Edinburgh and Director of the Arts and Humanities Research Council (AHRC) Research Centre for Studies in Intellectual Property and Technology Law. His research interests include the role of law in promoting and regulating science, medicine and technology.

Mairi Levitt studied sociology and religious studies at Edinburgh University and Exeter University. She is currently Senior Lecturer in the Department of Philosophy, Lancaster University. Her research interests are in the public understanding of science, the new genetics, empirical bioethics and children's values and religiosity.

Katherine Littler is a Policy Adviser in the Strategic Planning and Policy Unit at the Wellcome Trust. She joined the Trust in 2005, and works primarily on policy issues related to biobanks, cohorts studies and genome-wide association studies, human tissue research and data sharing in public health and epidemiological research. Her background is in law and medical ethics.

Peter Mills leads the Secretariat of the Human Genetics Commission (HGC), which is based within the Department of Health. The HGC is the Government's advisory body on developments in human genetics and their ethical, legal, social and economic implications. Before moving to the HGC, Peter worked for the Human Fertilisation and Embryology Authority (HFEA) where he led a number of high-profile policy reviews. Before joining the HFEA, Peter had a brief career in publishing.

Catherine Moody is a programme manager working for the Neurosciences and Mental Health Board at the UK Medical Research Council (MRC), and acts as an MRC contact person for the EGC. Her responsibilities for research at the MRC include clinical neurology, imaging technology and neuropathology. With an early career in biomedical research, Catherine has held a number of positions within the MRC and for three years was seconded to the Nuffield Council on Bioethics.

Roger Moore, EGC member, is an engineer by profession with broad interests in public policy and citizen involvement. In 2006 he retired as chief executive of the NHS Appointments Commission after a varied career within academia, the Department of Health and the National Health Service.

Paul Myatt, a Governance Policy Officer at the General Medical Council (GMC), manages the new GMC Reference Community. After completing a degree in Philosophy, Politics, and Economics, he has spent the last three years undertaking a variety of work within the GMC's Strategy and Planning Unit.

Tracey Phillips, EGC member, is a business and management consultant who has worked on design and implementation of quality management systems, business plan development, start-up support, stakeholder engagement and implementation and the audit of health and safety, environmental and other regulatory standards. Her professional work focuses on public policy, in particular in the fields of public health, social welfare and community cohesion.

Martin Richards, Vice-Chair of the EGC, is Emeritus Professor of Family Research and former Director of the Centre for Family Research, University of Cambridge. He founded the Centre in 1967. His research as a social scientist focuses on parent-child relationships, aspects of family life and genetics and reproductive technologies.

Andrew Russell, EGC member, recently retired as Chief Executive of the Association for Spina Bifida & Hydrocephalus, after a career working with disabled people, developing services in the UK and overseas, and managing a research programme. He is experienced in campaigning on policy issues, and has a strong interest in user representation. He is a Board member of the UK Clinical Research Collaboration and a former Chair of the Neurological Alliance.

Cathleen Schulte is a Policy Manager in the Human Genetics Commission Secretariat. Before moving to the Department of Health, she was Committee Specialist to the House of Lords Science and Technology Committee. Previously she worked as a postdoctoral scientist and she has an MA in health care ethics and law.

Margaret Shotter, EGC member, was until recently Associate Director for Research Ethics at the University of British Columbia, Canada. In this role she provided strategic planning and advice to the Vice-President of Research on ethical and regulatory aspects of human subject research at the University and all its affiliated research institutions.

Barry Taylor, who assists the EGC with media-related matters, is Communications Director at Bristol University. He is responsible for corporate communications, public engagement and major events. He worked in the arts for many years, as well as in local government, where he was closely involved in efforts to strengthen local democracy.

Andrew Trehearne is Head of Communications at UK Biobank, a post he has held for almost three years, having joined the project just before the first assessment centre opened. Prior to joining UK Biobank, he worked within the press teams for a number of high-profile UK charities, including Leukaemia Research Fund and Imperial Cancer Research Fund (now Cancer Research UK). Andrew is a trained journalist, having worked on local and regional newspapers.

5 Biographies

Paolo Vineis, EGC member, is Chair of Environmental Epidemiology at Imperial College London. His research interests include the development and application of biomarkers to environmental and cancer epidemiology. With an interest in ethical issues, he has published several papers on the implications of genetic testing and sits on Italy's College of Physicians' ethics committee.

Tom Wakeford, Director of Co-inquiry and Public Engagement at the PEALS Research Centre, Newcastle University, has worked on a range of approaches that aim to bridge the accountability gap between citizens and science and technology policy. The author of a number of books and articles, he recently co-edited *Empowered Participation* (IIED, 2008) a collection of case studies relevant to this area.

Kate Weiner is a senior research fellow at the Institute for Science and Society, University of Nottingham. She is a sociologist of medicine, health and technology with an interest in lay and professional knowledge, and lay involvement in science and science policy. Her work has mainly focussed on the areas of genetics and heart disease. Her current research is looking at more mundane technologies – cholesterol-lowering foods.

Heather Widdows, EGC member, is Professor of Global Ethics at the University of Birmingham where she teaches moral philosophy and bioethics. She is Lead Editor of the *Journal of Global Ethics* and on the editorial board of *Globalizations*, *Health Care Analysis* and *Asian Bioethics Review*. Her publications include a recently published collection on *The Governance of Genetic Information* (CUP) and she has published widely on the issues of genetic ethics and governance.

David Winickoff, Assistant Professor of Bioethics and Society at the University of California, Berkeley, develops policy for public and private institutions that helps guide and govern innovation in the life sciences. He has worked on biobanks, race-based pharmaceuticals, stem cell research, food safety, and the role of science in international trade law. Trained at Yale University, Harvard Law School and the University of Cambridge, David is currently working on the ethics and politics of commercialising publicly funded research.

Philippa Yeeles is Joint Director of Operations at the UK Clinical Research Collaboration (www.ukcrc.org) where much of her work focuses on developing patient and public involvement across the activities of the organisation. Prior to this Philippa worked for INVOLVE, a national advisory group funded by the National Institute for Health Research that supports and promotes active public involvement in NHS, public health and social care research.

6 Background paper from December 2009

6.1 An introduction to UK Biobank and the Ethics and Governance Council

The UK Biobank project was launched in 2007 with the aim of establishing a resource that will support a diverse range of health-related research intended to improve the prevention, diagnosis and treatment of illness and the promotion of health throughout society. As of 1 December 2009, 403,308 people have agreed to participate in the project.

Participation involves attending a dedicated, local recruitment centre during which the individuals are asked to provide consent to participate in the project. Participation involves providing information about their health, lifestyle, memory, work and family history; undergoing a few physical measurements (including ocular, blood pressure, pulse rate, height and weight); providing biological samples (including blood and urine); allowing UK Biobank to access information about their health through their health-related records (including their NHS medical record); and granting permission for researchers to access their data and samples for uses that meet the purpose of the project.

UK Biobank, a charitable company limited by guarantee, is the legal owner and steward of the database and sample collection. UK Biobank itself will not carry out research on the stored data and samples but has the responsibility to create and maintain the resource and manage access to this by those who wish to use it.

The project operates within the requirements of an 'Ethics and Governance Framework' (EGF). The EGF is a document that was specifically developed for this project and describes a series of standards to which UK Biobank will operate during the creation, maintenance and use of the resource. In addition, it elaborates on the commitments of UK Biobank and its personnel to those participating in the project and to researchers and the public more broadly.

The EGF addresses key ethical considerations and describes the governance arrangements of the study. For example, the EGF:

- Establishes that consent will be sought 'to participate in UK Biobank'. This is based on an explanation and understanding of a number of features of participation (such as the kinds of information and samples that will be collected at enrolment and the possibility of being re-contacted in future by UK Biobank)
- Affirms the right to withdraw at any time
- Makes a commitment to protecting the confidentiality of both samples and data

- Describes the broad benefit-sharing that will be required (including the obligatory publication of findings and accessible archiving of data and findings for future use)
- Describes the principles which govern access to the resource by researchers
- Describes the arrangements for management and accountability
- Describes the project's commitment to ongoing engagement with participants and the public.

The Framework is a 'living' document that is publicly available on UK Biobank's website. It will be revised from time to time in the light of changes, for example, to applicable laws. UK Biobank is the author of the framework and is responsible for discharging the obligations that it embodies.

The principal funders of the project – the Wellcome Trust and the Medical Research Council – decided to take the governance of UK Biobank one step further by forming an independent advisory committee with the responsibility of monitoring UK Biobank's conformance with the EGF. The UK Biobank Ethics and Governance Council was formed in November 2004 with the following remit:

- To act as an independent guardian of the EGF and to advise on its revision
- To monitor and report publicly on the conformity of the UK Biobank project with the EGF
- To advise more generally on the interests of research participants and the general public in relation to UK Biobank.

UK Biobank and the EGC have separate and distinct roles and responsibilities in relation to the project. Both may be considered to have an obligation to involve participants and other publics in their decision-making, albeit for potentially different reasons. The next section describes how publics were involved during the development stages of the project and the initiatives undertaken by UK Biobank and the EGC in recent years.

6.2 How publics have been involved

6.2.1 During the development of the project

Public consultation played a key role during the development of UK Biobank and in particular during the development of the EGF. Indeed, it was through early consultations, primarily commissioned by the project's funders, that the idea of an independent Ethics and Governance Council arose and was developed.³

The consultations can be categorised into three stages: First, an initial consultation in 2002 set out to explore and address questions of public trust in the context of (what was then) the hypothetical 'Biobank UK' project. Second, a draft EGF was used as the basis of two further consultations, the results of which directly informed the further development of the Framework.⁴ Thirdly, the final draft EGF was published on the web for comment.⁵ Since the launch of the project in 2007 the communications activities have largely transferred from the project's funders to UK Biobank and the EGC with their respective roles.

6.2.2 The EGC involving publics

The Council is charged to advise UK Biobank on the interests of research participants and the general public. These interests are a core theme that runs through both the Council's advisory and monitoring roles and, reflecting their importance, the EGC has developed a number of strategies through which it aims to learn about these interests.

The EGC holds at least one public meeting a year with the explicit purpose of gauging attendees' views on the project so that it might advise UK Biobank on such interests. The meetings are generally held in towns where UK Biobank is recruiting and marketing of the event is targeted to participants through UK Biobank's assessment centres. The Council has developed the meeting format over time to maximise active engagement and debate (for example, by allowing plenty of time for discussion, through small group discussions and by concluding each meeting with 'drinks and nibbles' so conversations can continue in an informal setting). In response to this and other interactions with the public, the Council has developed a series of Frequently Asked Questions for its website, which grows with the experiences of the Council. Public meetings have taken place in Manchester, London, Oxford, Cardiff and Edinburgh; the next meeting is planned for March 2010 in Sheffield.

The Council has the ability to commission research if it considers a particular topic to require investigation. In 2007 it commissioned a scoping study to investigate and summarise the work that has already been performed regarding the public's attitude to UK Biobank-

related issues.⁶ This study informed the EGC of the current literature in this area and in addition identified gaps in the literature, namely issues relating to access broadly and more specifically to commercialisation and benefit sharing. Having identified this gap the Council then commissioned a public attitude survey to investigate these issues in more details through the use of a postal questionnaire, telephone interviews and focus group work.⁷

The Council has produced a list of key implications and messages from its commissioned reports, which is published on the EGC website in a document entitled '*Advising on the public interest and the public good*'. This document summarises the findings of the commissioned reports in the context of their application to the Council's activities. This summary is a 'living' document which will be revised over time to take account of the Council's new thinking on the interpretations of 'public interest' and 'public good' (for example, in response to further commissioned public attitude work or future experiences).

EGC leaflets and annual reports are made available to participants at UK Biobank assessment centres and meeting reports are available on its website. The leaflets, annual reports and website all contain the EGC Secretary's contact details and readers are encouraged to write to the Council if they have queries or comments about UK Biobank or about the Council's own work.

3 The report '*Biobank UK: A Question of Trust: consultations exploring and addressing questions of public trust*' (2002) recommended that 'some form of oversight body should be established and that the body should be capable of acting independently of the user and sponsors.' Any such body 'should ensure that standards of behaviour and ethics are maintained and continued to reflect the public mood as the public consensus changes but within the original terms of consent given by volunteers.' Available at www.ukbiobank.ac.uk/ethics/consult.php

4 People Science and Policy Ltd, '*UK Biobank Consultative Ethics and Governance Framework*' (May 2003); Opinion Leader Research, '*Summary of UK Biobank Consultation on the Ethics and Governance Framework*' (August 2003). Available at www.ukbiobank.ac.uk/ethics/consult.php

5 UK Biobank funders, '*UK Biobank Ethics and Governance Framework: Summary of Comments on Version 1*' (May 2004). Available at www.wellcome.ac.uk/About-us/Publications/Reports/Biomedical-ethics/WTD003284.htm

6 Joanne Sumner, '*Public attitudes to biobank and related ethics and governance issues*' (2 January 2007). Available at www.egcukbiobank.org.uk/meetingsandreports

7 Andrew Webster, Nik Brown, Conor Douglas, Graham Lewis, Jane Kaye, Richard Tutton and Nick Williams, '*Public attitudes to third party access and benefit sharing: their application to UK Biobank*' (30 June 2008). Available at www.egcukbiobank.org.uk/meetingsandreports

The Secretary receives external enquiries on a regular basis from participants and other members of the public and the Council has sought to engage in the public forum of publications like *The Lancet* on queries about UK Biobank and the Council's role.⁸

6.2.3 UK Biobank involving publics

UK Biobank has established a strong programme of awareness raising that it applies to each new town or city in which it opens an assessment centre and, through national media coverage, has also sought to inform members of the public across the country. Regional TV, radio, and daily and weekly local newspapers are engaged when the first invitations to participate in the project are mailed and, once again, on the first day that an assessment centre opens. BBC Radio has been most supportive, though the regional daily press have been used successfully, most notably when a member of the local editorial team has written a first-person piece having been through the assessment process. Coverage over the ensuing weeks and months typically takes the form of letters to editors as notable recruitment totals are reached. Local side-of-bus advertising in the first weeks of an assessment centre opening has also raised profile and generated interest in the project. UK Biobank also contacts a wide range of groups and organisations (local health services, disability and religious groups, luncheon groups, pubs, cafes, laundrettes, etc.) with literature and posters, as well as businesses and local doctors, MPs and key members of staff at PCTs. UK Biobank has undertaken a limited amount of radio advertising (Edinburgh; Liverpool; Kismat, Punjabi and Sunrise radio stations in west London and Birmingham), which has also generated some editorial leads. Of note, perhaps, is how little media interest a study like UK Biobank generates (given the project will contact all 40-to-69 year olds in a given circulation area, follow their health over 30 years and collect samples of tissue for DNA analysis), unless the story is actively pushed by UK Biobank.

In line with UK Biobank's commitment to 'ongoing engagement with participants and the public', the project is developing its long-term communications strategy, which will be based largely, but not exclusively, around the internet. UK Biobank has a high proportion of email addresses and mobile phone numbers of participants and proposes to alert them to project developments in this way, directing them to the UK Biobank website for follow-up. Participants will be able to provide change of address details on the website. Those without access to the internet will be sent hard copies of a newsletter in the post. The project may wish to attend local 'science functions' and host annual national or regional conference events for participants and the project's scientific supporters. Researchers

wishing to use the resource (or already having done so) could be invited and key findings could be presented. A vital role for the website will be to ensure that as much information as possible about the use of the resource is provided to participants, but also to generate interest among the scientific community in order to ensure that the resource is used for improving health.

In addition to the awareness raising and the provision of information, the project has actively undertaken surveys of its participants, as well as actively sought out ongoing feedback (web and assessment centres) as the project has unfolded. Survey work of participants has been used to assess participant's views on the consent process and on their understanding of the project more generally. UK Biobank intends to conduct further survey work in the last few assessment centres and to conduct a number of more in-depth follow-up interviews with respondents.

6.3 The impetus for the workshop

The idea of holding a workshop on involving publics in biobank research and governance arose during the development of the EGC's workplan 2009–2010. The workplan itself was requested by the Wellcome Trust and Medical Research Council as one outcome of their 2008 funders' review of the EGC's activities. In their recommendations for future activities the funders acknowledged that the EGC had developed and implemented a strong public engagement programme within the UK while noting that for the future, it will be important for the EGC to consider which mechanisms of engagement and communication with the public are best undertaken by the EGC, which by Biobank directly and which by the funders.

The question of how participants can be involved with the project in the long-term, and how their interests can be represented in biobanking activities, has often been raised with the EGC, both at academic conferences and by members of the public at the Council's public meetings. The Ethics and Governance Framework (EGF) offers one possible method when it states that 'UK Biobank may also establish a participants' panel with a clear remit that is as representative as possible of the UK Biobank population and able to express views typical of the participants generally'.⁹ To date, UK Biobank has not chosen to form such a panel although the possibility remains open.

⁸ Graeme Laurie, 'Role of the UK Biobank Ethics and Governance Council' (Correspondence) *The Lancet* 374: 1676 (2009).

⁹ EGF I.B.4 available at www.ukbiobank.ac.uk/ethics/egf.php

The EGF also states UK Biobank's commitment that it 'will look for a variety of ways for communicating with (including listening to) participants, the general public, research users and the scientific community' (emphasis added).¹⁰ UK Biobank is currently in the process of developing its long-term communications strategy which should address the question of how it intends to 'listen to' participants in the future.

The Council's Modus Operandi (MO) states that 'in order to advise UK Biobank on operating in accordance with the interests of participants and the public, the Council will develop appropriate ways of engaging with participants and the public'. As mentioned in the previous section, the Council has developed a number of strategies through which it aims to ascertain these interests so that they are represented in its deliberations (for example, through public meetings and commissioned surveys).

The public can have an impact on UK Biobank and the EGC through all of these strategies although, arguably, the greatest impact might be achieved through representation on the project's governance bodies with participants embedded within the decision-making process. The EGC's MO details that 'the Council may, in due course, choose to include up to two UK Biobank participants in its membership'. At least three of the current Council members are UK Biobank participants, but this is by chance rather than any explicit decision to specifically target participants through the EGC's recruitment process. A question remains for the Council over whether or not it should specifically target participants in its next round of recruitment.

The difficulty of involving participants and representing their interests is not insignificant given the size of the cohort and the varied interests that are likely to exist within such a group. For the purposes of this workshop it is proposed that 'representation' is not thought of as the ability of a few participants to speak on behalf of the whole cohort, nor does it suggest some statistical representation. Instead, it should be considered in terms of participants who can speak from their experience as members of UK Biobank's cohort and provide reflections on a range of some of the interests within that cohort as a way to better inform decision-making within UK Biobank.

The provisions in the EGF and the remit and MO of the Council clearly demonstrate an intention and desire that the views of participants and other publics are taken into consideration during UK Biobank and the EGC's decision-making. As UK Biobank moves from the recruitment to the access phase it seems timely to reflect on the provisions in the EGF and on current practice and to ask why, how and when participants and publics might be involved, and how their views ought to be represented.

6.4 The aims of the workshop

The aim of the workshop is to inform the EGC and consequently UK Biobank itself about a number of different methods of involvement so that it might consider the contours of various methods which may be of benefit to UK Biobank, the EGC and the funders. The aim is not to identify one method in favour of another but to consider the desirability of each method and the circumstances in which each method might be applicable.

The workshop intends to explore the following general questions:

- Why involve publics?¹¹
- What does it mean to involve publics and what role would they play?
- How can the EGC and UK Biobank involve publics effectively and well?

The workshop will assist the Council by providing evidence for how it might consider these issues in terms of its own work and in terms of its advice to UK Biobank. For example, it might help address the questions:

- Are the current methods of involving publics employed by UK Biobank and the Council sufficient in terms of garnering publics' views?
- Would a participant panel as envisaged in the EGF be a good model to adopt?
- Should there be an explicit policy expressing the desirability of participant representation on the Council?
- What other methods are available and are any of them desirable?
- How do you find publics who would be willing to be involved and what would their role be?
- Would such publics advise UK Biobank, the EGC or the funders?
- Is any such model a duplication of effort, for example overlapping with or potentially replacing the work of the EGC?

¹⁰ EGF I.B.4 available at www.ukbiobank.ac.uk/ethics/egf.php

¹¹ UK Biobank participants are the focus of the Council advisory role, although its remit extends to advising on the interests of the general public more broadly.

6.5 Desired outcomes and outputs

The workshop should provide the EGC with an evidence base from which it will:

- Evaluate its own current strategy for involving publics
- Decide on the need for changes to its strategy
- Advise UK Biobank on its involvement strategy
- Advise the funders on the circumstances in which they may be best placed to undertake a particular method (rather than either UK Biobank or the EGC undertaking the method).

A report of the workshop will describe the day's proceedings, including an outline of the presentations and discussions. The report will also provide an account of the EGC's reflections on its own and UK Biobank's involvement strategies in light of the workshop.

The Council hopes that the workshop and the final report might serve as a platform for discussion in other projects about participant involvement.

7 Contact details

UK Biobank Ethics and Governance Council

We welcome any comment about this report, about UK Biobank or the EGC's methods of involving publics. You can contact our Secretary, Ms Adrienne Hunt, at the address below.

If you would like further information about our work more broadly, we recommend that you have a look at our website (www.egcukbiobank.org.uk). We post all our meeting reports there. If you do not have access to the internet, please request hard copies from Adrienne by writing to her at the address below:

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UK Biobank

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