

UK Biobank: a model for public engagement?

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Whilst in other applications of genetic technology the public debate has begun only when a piece of research has been completed, public consultations on biobanking began in 2000, before the funding for UK Biobank was even agreed, and have continued throughout its development. UK Biobank has obvious attractions for the British public. It is being set up specifically as a resource for research into common diseases that are relevant to everyone, rather than rare genetic disorders unknown to most. The only diseases mentioned on the 'about UK Biobank' web page are cancer, heart disease, diabetes and Alzheimer's disease¹. The public are encouraged to be involved by the promise of 'a better life for our children and grandchildren' and 'enormous potential to result in improvements to health of the UK population' through the National Health Service.²

Ensuring public support

Despite these selling points it was recognised by the Medical Research Council (MRC) and Wellcome Trust from the start, that work would have to be done to ensure that UK Biobank would be a success³. The early consultations indicated reasons why public support could not be taken for granted. There was recognition of a problem of trust in science and science governance in the UK with the 'BSE crisis' and the media furore over GM food following the reporting of Pusztai's research with rats and GM potatoes and his concerns over GM food⁴. The first public consultation on UK Biobank stated that genetic research had 'a raft of unhelpful negative associations, based sometimes on misinformation and mistaken assumptions'⁵. In contrast 'some people were better informed...and tended to have a more favourable view'⁶. UK Biobank has taken the view, found in many policy documents in the field of genetics, that transparency and openness is the key to increasing public confidence and trust⁷. The website contains a wealth of information including on-line minutes of meetings, results of public and stakeholder consultations, names and biographies of committee members and, with a push under the Freedom of Information Act, the reviewers' reports on the scientific protocol⁸.

So UK Biobank might be seen as a model for public involvement having commissioned eight consultations with different groups between 2000 and 2003 and provided open access to the findings⁹. The public were consulted through surveys, focus groups and a people's panel before the plans were finalised; there were lay members on the committee devising the ethics and governance framework and on the committee devising the scientific protocol. Different publics were consulted throughout the process of planning the Biobank, for example, there was a consultation once the Ethics and Governance framework was devised and the views of those taking part in the pilot project are currently being gathered (the pilot began in October 2005).

Tackling the ethics

Many of the traditional ethical concerns about medical research were avoided altogether by the protocol for UK Biobank. The age group chosen does not include children who cannot consent, would be unlikely¹⁰ to include pregnant women or women planning a pregnancy, targets the currently healthy rather than vulnerable sick and avoids the elderly. The request to donate will be made independently of any treatment being received.

Other ethical boxes are ticked under the arrangements for the biobank. There will be:

- Voluntary participation
- Individual consent with general information on data uses and types of research
- Right to withdraw at any time
- No property rights over donated sample
- Access controlled using the existing system of research ethics committees
- An independent Ethics and Governance Council
- Security arrangements and assurances of confidentiality

What were the public *not* asked about?

The public were regularly consulted as the project developed in order to find out what would increase public interest and confidence and so ensure enough people would participate. Thus, in the early stages, consultations asked about general attitudes to genetic research and, later on, asked people to consider technical questions about how samples should be collected, issues of consent and access. The public were not invited to consider more fundamental questions about Biobank itself, for example, the priorities of commercial users versus the public interest, the likelihood of benefits set against other possible uses of those resources, the content of regulations and who would be enforcing them¹¹. These sorts of concerns were covered by assurances that UK Biobank will ‘Ensure that UK Biobank is used in the public interest’, that as a charitable company ‘it will only be allowed to act in the public good’, that applications to use the samples would be subject to ethical scrutiny by research ethics committees and so on. As numerous studies have already shown, the public (or rather the diverse ‘publics’) have expertise from their lived experience that leads them to raise issues that may be overlooked by scientists, policy makers and others acting in their capacity of ‘expert’¹². For example, ‘public benefit’ may be a nice sounding phrase but who decides what is a public benefit, how are the public involved in the decisions and what happens when there are disputes about what is and is not a public benefit?

Power of veto

Power currently rests with the Board of Directors consisting of a healthcare policy expert, representatives of the funding bodies (Wellcome Trust, Medical Research Council and Department of Health), Professors of General Practice and Clinical Medicine and a chartered accountant. Not only are there no lay representatives, there are no ethicists or social scientists. The scientific committee has twelve professors in epidemiology, public health and other areas of medicine, an ex-nurse, the ex-chair of

an NHS Trust and a professor of social policy. The Ethics and Governance Committee includes a marketing consultant, two people involved in consumer/patient interests, a barrister, a medical doctor, a professor of pharmacology and three ethical experts. This committee has been set up to safeguard donors and the public in general by reviewing the users of data and the types of research that are proposed. However, it is not the Ethics and Governance Committee that has the power of veto over the use of data or samples. This power belongs to the Board of Directors. A member of the scientific committee sits on the Board of Directors but there is no member from the Ethics and Governance Committee. This does not fulfil the promise in the Government White Paper (2003) that there would be an ‘independent monitoring body’ with the power of veto i.e. presumably it was intended that such a body would be independent of the funding bodies¹³.

If the Ethics and Governance Committee feels that a particular application is not in the public interest, or is unethical for any other reason, they can report publicly on their views. If they raise concerns and are not satisfied with the response from the Board of Directors they could resign. Given the acknowledgement in early UKBiobank consultations of the influence of the media in the field of genetics, this seems an unwise limitation. If the committee did ‘go public’ no doubt there would be extensive media coverage and a subsequent effect on recruitment/retention of donors.

Upstream but powerless to control the flow or dam the waters!

‘Upstream’ public engagement involves the public at all stages of scientific innovation and involves them in the direction of policy rather than simply inviting them to comment on existing arrangements¹⁴. In UK Biobank the public were involved ‘upstream’ in the sense of being involved early on in the project’s progress but were not asked about the direction of the stream or its final destination. There was ‘upstream’ ethics engagement too, involving bioethicists, social scientists and other non-scientists whose task was to anticipate the boulders and other obstacles and smooth the flow of the stream. They are not able to control the direction of the river or to dam it if they feel it should be stopped. Both public and ethicists have played a part in smoothing the path of the stream but, under current plans, control lies elsewhere.

¹ <http://www.ukbiobank.ac.uk/about.php>.

² Press release, 2002, UK Biobank website http://www.wellcome.ac.uk/doc_WTD002895.html

³ Funding for the UK Biobank comes from the Medical Research Council; which is funded by the UK Government; the Wellcome Trust which is a medical research charity, the Department of Health and the Scottish Executive.

⁴ Horton R. (1999) Commentary: Genetically modified foods: ‘absurd’ concern or welcome dialogue? *Lancet* 354: 1315

Lancet (1999) Editorial: Health risks of genetically modified foods. *Lancet* 353:1811

⁵ MRC/Wellcome Trust (2000) *Public perceptions of the collection of human biological samples*. Qualitative research to explore public perceptions of human biological samples Report prepared by Cragg Ross Dawson for the Wellcome Trust and Medical Research Council p.25f

⁶ *ibid*

⁷ Jones M. and Salter B. (2003) The governance of human genetics: policy discourse and constructions of public trust. *New Genetics and Society* 22:1 pp.21-41.

⁸ See <http://www.ukbiobank.ac.uk>

⁹ <http://www.ukbiobank.ac.uk/ethics/consultations.php>

¹⁰ Although the age range for participation has now been widened to 40-69 (from 45-69).

¹¹ All these sorts of concerns were raised in focus groups held with the general public (mixed age, sex, social background) discussing perceptions of privacy and trust in relation to personal medical and genetic data see Levitt M. and Weldon S. (2005) 'A well placed trust? Public perceptions of the governance of DNA databases' *Critical Public Health* 15:4

¹² For a summary of purpose, methods and activities see Sue Weldon (2004) *Public engagement in genetics: a review of current practice in the UK* <http://www.cesagen.lancs.ac.uk/resources/papers.htm>

¹³ Department of Health (2003) *Our inheritance our future. Realising the potential of genetics in the NHS*

http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Genetics/GeneticsGeneralInformation/GeneticsGeneralArticle/fs/en?CONTENT_ID=4016430&chk=RnGBgL

The full paragraph reads 'An independent monitoring body will also be established to ensure that samples of genetic material are taken with the fully informed consent of the participants and that procedures to protect confidentiality are strictly adhered to. This body will have the power to veto uses of the data or samples that it considers to be against the interests of the participants or likely to damage the reputation of the study'.(para 5.37)

¹⁴ Wilsden and Willis (2004) *See-through Science. Why public engagement needs to move upstream*. London: Demos