

UK Biobank – Half a Million Steps to a Healthier Future

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In April 2007 a small, mixed group of people entered a commercial office building in Manchester city centre to embark on one of the most ambitious health research projects ever undertaken.

Their ranks, over the course of that week, swelled to 300 – and now stand at more than 20,000, and are growing all the time.

Another 480,000 people aged 40-69 will follow in their footsteps over the next four years, and most, if the first participants are anything to go by, will be motivated by one simple desire – to improve the health of future generations.

So, after the years of deliberation, discussion, review and successful piloting, UK Biobank, a prospective study of lifestyle, environmental and genetic determinants of a wide range of diseases, is finally on its way.

UK Biobank assessment centres are now recruiting participants in Oxford, Manchester, Glasgow and Cardiff, with others planned in towns and cities across the country as the programme rolls out.

Participants in this visionary medical project are helping to build an unparalleled resource to give scientists of the future access to new information that will help cure and prevent many life-threatening, painful and debilitating illnesses such as cancer, heart disease, diabetes, stroke, dementia, arthritis and depression.

Crucial to this is that participants answer questions about their current health and lifestyle, allow UK Biobank to take some standard body measurements (blood pressure, bone density, lung function, height, weight, grip strength and body mass), that they donate small samples of blood and urine for long-term storage and

analysis, and that they consent to follow-up of their health over many years (electronically, using health records).

This will provide scientists of the future with the most detailed information ever collected to help determine why some people get certain illnesses and others do not – paving the way for better prevention and treatment.

UK Biobank's non-intrusive approach to the detailed questionnaire – interview by touch-screen computer, rather than by a person – is resulting in high responses to all questions, even some which may stop you in your tracks. Would you feel comfortable telling an interviewer how many sexual partners you have had? Probably not, but most participants respond to all the computer's questions.

Working together

UK Biobank is a massive project and all those centrally involved have learnt an enormous amount during its inception and now its delivery.

It is funded by the Wellcome Trust, the Medical Research Council, the Department of Health, the Scottish Executive and the Northwest Regional Development Agency. It is hosted by the University of Manchester, has the support of the National Health Service (NHS) and the Welsh Assembly and is a collaborative effort between 22 UK universities.

Practical, scientific, ethical and legal questions have been addressed, from just how big should the study be, to what is the best recruitment strategy (bearing in mind costs and questions of privacy) for half a million people?

The approach has been discussed by the funders, scientists, ethicists and members of the public and,



throughout, UK Biobank has sought to deliver the 'gold standard' in prospective epidemiological study design. Many reviewers, including UK Biobank's prestigious International Scientific Advisory Board, which met in June, believe it is achieving that.

Building trust with participants is crucial to the long term success of the project. UK Biobank seeks dialogue with participants and their GPs before the first invitations are mailed. It has systems in place to ensure it responds quickly to concerns and worries.

Communication with participants takes a number of forms:

- An Information Leaflet enclosed with the letter of invitation;
- A Further Information Leaflet available on request;
- A UK Biobank website: www.ukbiobank.ac.uk;
- Information in: Welsh, Arabic, Chinese, Bengali, Turkish, Gujarati, Hindi, Polish, Russian, Urdu, Punjabi, Somali;
- A free telephone information service, six days a week (8am-7pm), which also allows participants to confirm and change appointment times;
- Senior UK Biobank staff available to respond to urgent calls that require immediate action (this escalation process underlines the importance with which UK Biobank takes all questions or concerns about the study);
- Alerting GPs to the fact that people registered with them will soon receive their invitations;

- Publicity campaigns involving local and regional media, as well as awareness raising side-of-bus adverts;
- Engaging with like-minded charities and researchers at universities across the country to enhance the resource.

Making contact

Contact details without any medical information are provided for people aged 40-69 years by the NHS centrally. The only information provided about an individual is their name, address, sex, date of birth, NHS number and general practice.

Approval for the release of this information in confidence for the purpose of inviting participants into the UK Biobank project was obtained from the Patient Information Advisory Group (PIAG) in accordance with Section 60 of the Health and Social Care Act. Confirmation that this processing of contact details complied with the Data Protection Act was obtained from the Office of the Information Commissioner.

The UK Biobank Protocol, including the approach to recruitment, has also been approved by the NHS North West Multicentre Research Ethics Committee (MREC).

UK Biobank understands the need for transparency at all stages of its development. Its continued integrity and good name is crucial to the long-term success of the project. Participants need to be able to trust in the project since it deals with the most sensitive, private matters of past, present and future health.

Storage and follow-up

Participants' blood and urine are being stored in specially constructed state-of-the-art facilities near Manchester. Computer equipment able to hold information anonymously and securely, but also able to match health updates with individual records and the relevant blood and urine samples, has also been developed.

Great care is taken to ensure the confidentiality of all data, and details that might identify participants are removed from any information and samples before they are provided to researchers.

Electronic follow-up is planned through various databases of health records, some of which already exist in an easily accessible national form (eg death and cancer registers; occupational and dental records; hospital episode statistics) and some that are being brought together in a national format through Connecting for Health (eg GP records).

UK Biobank is largely dependent on national sources for the provision of health care follow-up data for consented participants. Ideally, this data should be comprehensive and complete for each participant and should be routinely refreshed throughout the duration of the project.

This in itself is a challenge, though given the long-term nature of UK Biobank (it may be ten years before the resource accrues enough cases of a particular disease to begin analyses) a consistent and thorough approach should be possible.

Agreement will also be sought on the data requirements – how it will be structured and provided and how UK Biobank will know it is complete and accurate.

Robotics technology has come together in novel ways to allow accurate processing of 20,000 1.4ml tubes containing samples every day. And the practicalities of storage have been imaginatively addressed. Purpose built facilities use a 3D 'barcode' embedded into the container of each frozen sample to provide for rapid storage and retrieval by robots. The technology needs to withstand many years of sub-zero temperatures. With around 15 million aliquots eventually stored away, efficiency and accuracy here is essential.

It is important that we take a very structured approach to the custodianship of data in UK Biobank which means that, with core systems, we are pursuing ISO accreditation and are subjecting all key technologies to audit.

We have adopted a principle of complying with and helping to define appropriate data standards, which means that we are working to the HL7 standard (Health Level 7), which supports the development, promotion and implementation of standards in ways which meet the needs of the

healthcare community. This will improve our ability to link to external data sources and means that we are active in the international community (EU Framework 6 and proposed Framework 7), and working on harmonising data standards for biobanking worldwide.

Governance

The independent UK Biobank Ethics and Governance Council was established by the Wellcome Trust and the Medical Research Council (MRC) to act as guardian of the UK Biobank Ethics and Governance Framework. Its remit includes advising more generally on the interests of research participants and the general public in relation to UK Biobank. The EGC is chaired by Graham Laurie, Professor of Medical Jurisprudence at the University of Edinburgh.

The future

Any study as ambitious as UK Biobank will arouse comment and questions. The public interest in UK Biobank means it is important to monitor our levels of service and to respond and improve when appropriate.

Scientifically, the focus is on delivering enhancements to the dataset, ensuring the quality of the data so far recorded and encouraging widespread engagement with the whole UK health research and scientific communities, and, indeed, with researchers from overseas. Access to the health records that participants have so kindly agreed we can follow is also important.

UK Biobank is building a health resource for researchers from around the world. Access will be governed by strict ethics and scientific criteria that comply with its stated aims. An Access Policy is currently being framed and will soon be available on the UK Biobank website.

It has been a privilege to visit our assessment centres in recent months and find out what motivates people to join UK Biobank. The overwhelming desire is to do something positive to help improve the health of future generations. Belief that science can deliver is inspiring. We do bear that in mind all the time as we strive to make this project a major force for health improvement not just in the UK, but around the world.

Further information:

UK Biobank: www.ukbiobank.ac.uk or call Andrew Trehearne on 01865 743960

EGC: www.egcukbiobank.org.uk